

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

WILLOW INNOVATIONS, INC.,

Plaintiff and Counterclaim Defendant,

v.

CHIARO TECHNOLOGY, LTD.,

Defendant and Counterclaim Plaintiff.

Civil Action No. 2:23-cv-00229

JURY TRIAL DEMANDED

**CHIARO TECHNOLOGY, LTD.'S ANSWER TO WILLOW'S SECOND AMENDED
COMPLAINT FOR PATENT INFRINGEMENT**

Defendant/Counterclaim Plaintiff Chiaro Technology Ltd. ("Defendant" or "Elvie") hereby submits its Answer, Defenses, and Counterclaims to Willow's Second Amended Complaint for Patent Infringement ("Complaint") filed by Willow Innovations, Inc. ("Willow" or "Plaintiff"). Any and all allegations contained in Plaintiff's Complaint not expressly admitted in this Answer are denied.

GENERAL DENIAL

Elvie denies all allegations in Plaintiff's Complaint except for those specifically admitted below. With respect to the allegations made in the Complaint, upon knowledge with respect to Elvie's own acts, and upon information and belief as to other matters, Elvie responds and alleges as follows:

THE PARTIES

1. Plaintiff Willow Innovations, Incorporated is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1975 El Camino Real, Suite 306, Mountain View, CA 94040. On October 21, 2020,

Willow changed its name from “Exploramed NC7, Inc.” to “Willow Innovations, Inc.”

ANSWER: Elvie lacks sufficient knowledge and information to form a belief as to the truth of the allegations of Paragraph 1 as pled and denies those allegations on that basis.

2. Defendant Chiaro Technology, Limited is a corporation organized and existing under the laws of the United Kingdom, with its principal place of business at 63-66 Hatton Garden, EC1N 8LE, London, United Kingdom. On the information and belief, Elvie is the trading name of Chiaro Technology Limited and conducts business, either directly or through its agents, on an ongoing basis in this judicial district and elsewhere in the United States.

ANSWER: Elvie admits that Chiaro Technology, Limited is a corporation organized and existing under the laws of England and Wales, with its principal place of business at 63-66 Hatton Garden, EC1N 8LE, London, United Kingdom. Elvie further admits that Elvie is the trading name of Chiaro Technology Limited. Elvie denies the remaining allegations of Paragraph 2.

BACKGROUND

3. Traditional breast milk pumps were decades overdue for innovation. Enter the Willow Pump. Founded in 2014, Willow revolutionized the way women pump with the world’s first spillproof, in-bra wearable breast pump. Selected as one of TIME Magazine’s 25 Best Inventions, the Willow pump was the first to get rid of the heavy motors, tubes, and electrical cords—and put moms in control. Traditional pumps required nursing moms to sacrifice hours of their day connected to an electrical outlet or to a heavy, conspicuous appliance. Pumping in public required either exposing a breast in public, or relying on a public bathroom or similarly inconvenient location. Willow was the first to make it possible to pump anywhere, giving moms back their privacy, dignity, and freedom of movement. Since then, Willow has grown into a market leader, providing moms with industry-leading suction technology. Willow has gradually grown its array of product offerings, with a primary focus on the U.S.—the world’s largest market for breast pumps.

ANSWER: Paragraph 3 of the Complaint contains statements that are neither allegations nor averments to which a response is required. To the extent a response is required, Elvie lacks sufficient knowledge and information to form a belief as to the truth of the allegations of Paragraph 3 as pled and denies those allegations on that basis.

4. Also in 2014, Willow filed for its first United States patent application. It now holds more than 35 issued U.S. patents covering the functionality and designs of its products, with additional applications currently pending before the United States Patent Office (“USPTO”). In addition, Willow holds dozens of international patents in jurisdictions such as Australia, Singapore, China, Europe, Japan, Korea, Hong Kong, and the United Kingdom. To protect its hard-earned innovations, Willow provides notice to prospective infringers of its extensive patent portfolio via its website. <https://onewillow.com/about-willow/patents/>. This publication also satisfies the standard for constructive notice under 35 U.S.C. § 287(a) for purposes of virtual patent marking.

ANSWER: Paragraph 4 contains legal conclusions and allegations to which no response is required. To the extent a response is required, Elvie denies that Willow’s virtual patent marking provides sufficient notice to the public of each patent covering each of Willow’s products. Elvie otherwise lacks sufficient knowledge and information to form a belief as to the truth of the allegations of Paragraph 4 as pled and denies those allegations on that basis.

5. Today, Willow is a market leader in “femtech”—a shorthand term used to describe technology products and services that support women’s health. The femtech industry is projected to be worth \$50 billion by 2025. Willow’s product offerings include wearable pumps, containers, pumping bras, carrying bags, and other accessories. <https://onewillow.com/#>. Willow offers for sale these products via its website and through select retailers and online marketplaces, such as Target, Best Buy, buybuy Baby, and Amazon.

ANSWER: Paragraph 5 of the Complaint contains statements that are neither allegations nor averments to which a response is required. To the extent a response is required, Elvie lacks sufficient knowledge and information to form a belief as to the truth of the allegations of Paragraph 5 as pled and denies those allegations on that basis.

6. Elvie is based in the United Kingdom and launched its Elvie Pump system in 2018 at the London Fashion Week. <https://techcrunch.com/2018/09/14/kegel-trainer-startup-elvie-is-launching-a-smaller-smarter-breast-pump/>. Later that year, Elvie received clearance from the U.S. Food and Drug Administration to market the Elvie Pump in the U.S. https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181863.pdf. In its pre-market notification report submitted to the FDA, Elvie admitted that its breast pump is substantially equivalent to the Willow Pump. *See id.* (citing product code “HGX” to show the Willow Pump was an FDA-cleared predicate device to the Elvie Pump).

ANSWER: Elvie admits that it has its principal place of business in the United Kingdom. Elvie admits that it received clearance from the U.S. Food and Drug Administration to market the Elvie Pump in the United States and released its Pump system during the 2018 London Fashion Week. Elvie also states that the Medela Freestyle is the predicate device that is listed in the Elvie Pump 510(k) premarket notification. Elvie denies the remaining allegations of Paragraph 6.

7. Elvie has exploited Willow's patented technology to secure more than \$150 million in funding from investors. Most recently, in 2021, Elvie secured \$97 million in its Series C funding round. <https://techcrunch.com/2021/09/07/womens-health-tech-brand-elvie-tops-up-series-c-to-97m/>.

ANSWER: Elvie admits that it has secured Series C funding as of 2021. Elvie denies the remaining allegations of Paragraph 7.

8. Elvie has leveraged Willow's patents to establish itself as a major manufacturer and distributor of consumer breast feeding equipment. Willow brings this suit to protect its constitutional patent rights against Elvie's past and continued infringement.

ANSWER: Denied.

JURISDICTION AND VENUE

9. This is a civil action for patent infringement, false advertising, and unfair competition arising under the laws of the United States, 35 U.S.C. §§ 100 *et seq.* This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), and 1367(a).

ANSWER: Paragraph 9 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Elvie admits that Plaintiff purports to bring a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.* Further, Elvie does not contest subject matter jurisdiction over Plaintiff's claims under 28 U.S.C. §§ 1331, 1338(a), and 1367(a) for purposes of this this action only. Elvie specifically denies that any cause of action for false advertising or unfair competition arises under 35 U.S.C. §§ 100 *et seq.* Elvie denies the remaining allegations of Paragraph 9.

10. This Court has supplemental jurisdiction over Willow's unfair competition claim under Texas common law because it is so related to the federal false advertising claim that it forms part of the same case or controversy. Namely, Willow's unfair competition claim derives from the same nucleus of operative fact as the federal false advertising claim because both claims are based on Elvie's false and misleading advertisements in commerce regarding the alleged silence of the Elvie Pump. Thus, these claims will implicate overlapping facts and evidence.

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no response is required. To the extent a response is required, Elvie does not contest the Court's exercise of subject matter jurisdiction over it for purposes of this action only. Elvie denies the remaining allegations of Paragraph 10.

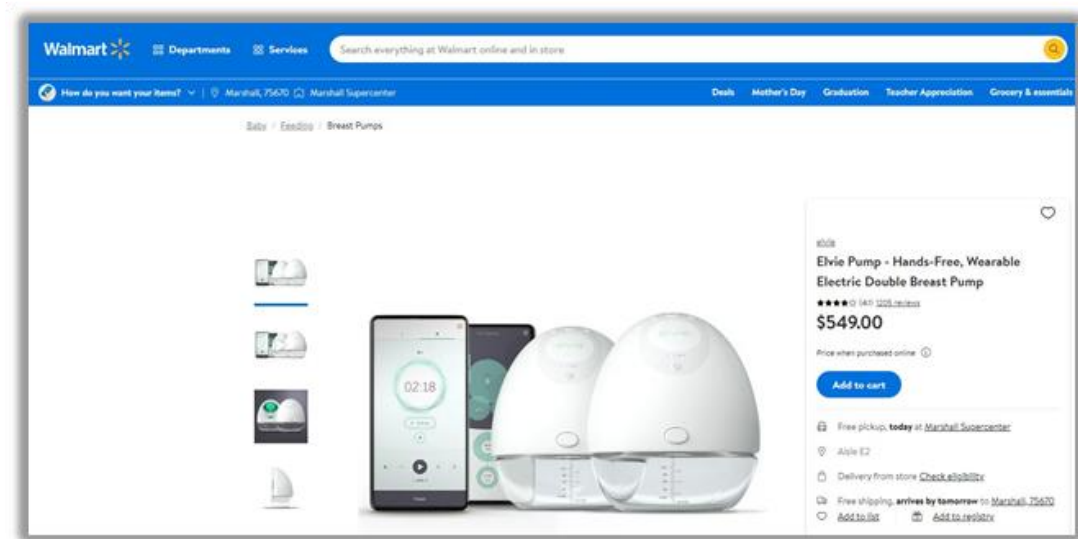
11. This Court has personal jurisdiction over Elvie at least because it (1) has committed acts of patent infringement and contributed to and induced acts of patent infringement by others in this District; (2) regularly did business or solicited business in this District; (3) engaged in other persistent courses of conduct and derived substantial revenue by its offering of infringing products and services and providing infringing products and services in this District; and (4) purposefully established substantial, systematic, and continuous contacts with this District and should have reasonably expected to be subject to suit here by its offering of infringing products and services and providing infringing products and services in this District.

ANSWER: Paragraph 11 contains legal conclusions and allegations to which no response is required. To the extent a response is required, Elvie does not contest the Court's exercise of personal jurisdiction over it for purposes of this action only. Elvie denies the remaining allegations of Paragraph 10.

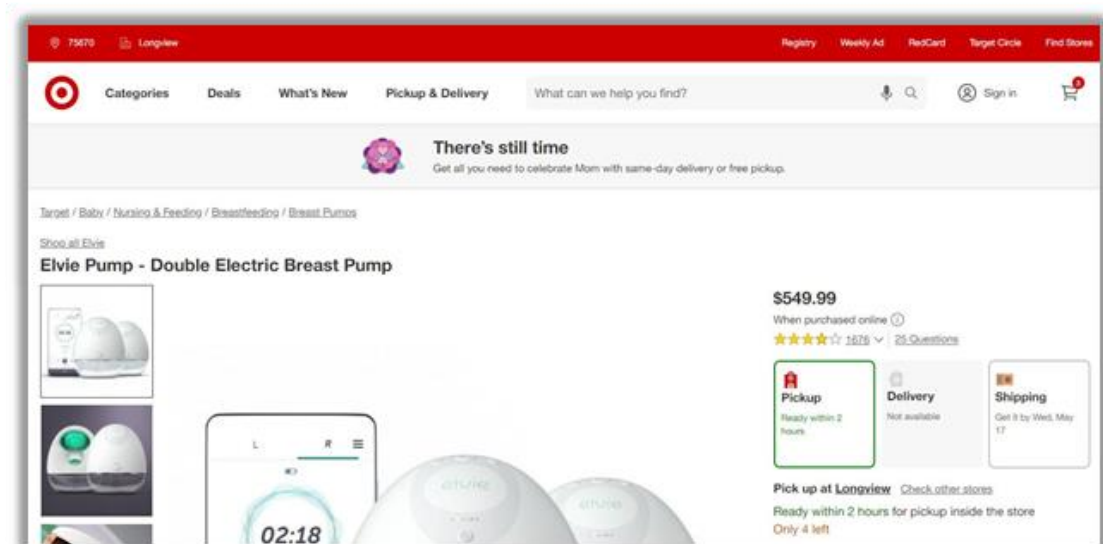
12. Elvie has sold their breast pumps and related products within this District via the following means:

- a. Through its own online store at <http://www.elvie.com>, customers—including those in this District and throughout Texas—can purchase Elvie's suite of products. Upon information and belief, Elvie uses its agents and distribution partners to direct infringing products purchased online to customers in this District. Elvie also uses its website to engage with and support its customers. For example, Elvie provides instructions for using the Elvie Pump through a variety of publicly-available resources, including product manuals, answers to common questions, and how-to videos. https://www.elvie.com/assets/manuals/elvie_pump_manual_en.pdf; <https://www.elvie.com/en-us/support/elvie-pump>.

- b. Elvie has authorized at least nine retailers and distributors to sell its products, as described at <https://www.elvie.com/en-us/partners/b2b-partners>. These partners include major retailers such as Walmart, Amazon, Target, Costco, and Best Buy—all of which maintain stores, warehouse facilities, and/or distribution centers in this District. As detailed below, customers in this District may purchase Elvie products from authorized sellers via (1) the authorized seller’s website; or (2) the authorized seller’s brick-and-mortar store located within the District:



Elvie Pump – Hands-Free, Wearable Electric Double Breast Pump, Walmart (last visited May 15, 2023), <https://www.walmart.com/ip/Elvie-Pump-Hands-Free-Wearable-Electric-Double-Breast-Pump/347662224?fulfillmentIntent=In-store&adsRedirect=true> (showing Elvie Double Electric Breast Pump is available for online purchase and also is in stock at Marshall Supercenter in Marshall, TX).



Elvie Pump – Double Electric Breast Pump, TARGET (last visited May 15, 2023), <https://www.target.com/p/elvie-pump-double-electric-breast-pump/-/A-75662623#lnk=sametab> (showing Elvie Double Electric Breast Pump is available for online purchase and also is in stock at Target in Longview, TX).

ANSWER: Elvie admits that it has made its products available for sale on its website, as well as other retailer websites including Walmart, Amazon, and Target. Elvie does not contest personal jurisdiction for purposes of this action only. Elvie denies the remaining allegations of Paragraph 11.

13. Elvie purposefully avails itself of the benefit of conducting business in Texas by marketing and selling its products to citizens in the state (including in this District). The United States is the largest market in the world for breast pump products, and Texas is the second largest state in the United States by population. Given the size of the market and the significant presence of retailers, distributors, and other business partners in the state, Elvie has specifically targeted Texas as a key market for its products. For example, in August 2022, Elvie’s Chief Commercial Officer, Aoife Zakaras-Nally, provided comments to the Houston Chronicle touting the benefits and commercial success of the Elvie Pump. <https://www.houstonchronicle.com/lifestyle/renew-houston/health/article/Breastfeeding-will-never-be-free-But-it-can-be-17339050.php?cmpid=gsa-chron-result>. Houston is a particularly important market for Elvie, given the size and reach of its medical community. *See id.* (Dr. Stan Spinner, chief medical officer of Texas Children’s Hospital based in Houston, describing the benefits of breastfeeding).

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no response is required. To the extent a response is required, Elvie admits that Plaintiff purports to present comments by Aoife Zakaras-Nally cited in the Houston Chronicle article from August 1, 2022, titled “Breastfeeding will never be free. But it can be made easier. Here’s how new technology helps moms.” Elvie denies the remaining allegations of Paragraph 13.

14. In addition, on information and belief, Elvie exercises control over its distributors, retailers, and other partners that conduct Elvie’s business in Texas. For example, Elvie limits its product warranty—ranging in duration from 90 days to two years from the date of purchase—to those products purchased directly from Elvie and its authorized sellers. *See* <https://www.elvie.com/en-us/warranty> (“[T]his limited warranty applies only to original purchasers of Elvie Product(s) that were purchased from Chiaro or a Chiaro authorized seller in the United States, unless otherwise

prohibited by law.”). On its website, Elvie provides instructions for anyone interested in becoming an authorized seller of Elvie products. <https://www.elvie.com/en-us/partners/b2b-partners>.

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no response is required. To the extent a response is required, Elvie admits that Plaintiff purports to present an incomplete selection or summary of text from Elvie’s webpages, but the actual and complete disclosure of the webpages speaks for themselves and are controlling. Elvie denies the remaining allegations of Paragraph 14.

15. Elvie, directly and through subsidiaries or intermediaries (including distributors, retailers, and others), has purposefully and voluntarily placed its infringing products into this District and into the stream of commerce with the intention and expectation that the infringing products will be purchased for use in Texas and in this District. Elvie has imported, offered for sale and sold, and continues to import, offer for sale and sell, infringing products for delivery and use in this District. Thus, Elvie has intentionally targeted Texas, and this District, for its business activities, and has purposefully availed itself of the benefits of conducting business in Texas such that it should reasonably anticipate being subject to its laws and the jurisdiction of its courts.

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no response is required. To the extent a response is required, Elvie does not contest the Court’s exercise of personal jurisdiction over it for purposes of this action only. Elvie denies the remaining allegations of Paragraph 15.

16. Venue is proper in this District under at least 28 U.S.C. §§ 1391(b), (c) and/or 1400(b). Venue is proper with respect to Elvie because it is a foreign entity that has committed acts of infringement in this District, as detailed throughout this Complaint. Elvie has committed and continues to commit acts of patent infringement in this District, by, among other things, directly and/or indirectly making, using, selling, offering to sell, or importing products that infringe one or more claims of the Patents-in-Suit.

ANSWER: Paragraph 16 contains legal conclusions and allegations to which no response is required. To the extent a response is required, Elvie does not contest venue for purposes of this action only. Elvie denies the remaining allegations of Paragraph 16.

THE ASSERTED PATENTS

17. This action involves seven asserted patents: U.S. Patent No. 10,398,816 (“the ’816 Patent”), U.S. Patent No. 10,434,228 (“the ’228 Patent”), U.S. Patent No. 10,625,005 (“the ’005 Patent”), U.S. Patent No. 10,722,624 (“the ’624 Patent”), U.S. Patent No. 11,185,619 (“the ’619 Patent”), U.S. Design Patent No. D832,995 (“the ’D995 Patent”), U.S. Design Patent No. D977,625 (“the ’D625 Patent”), and U.S. Patent No. 10,688,229 (“the ’229 Patent”) (collectively, the “Asserted Patents”).

ANSWER: Elvie denies that this action purportedly involves seven asserted patents, as Willow added an eighth patent in its First Amended Complaint: U.S. Patent No. 10,398,816 (“the ’816 Patent”); U.S. Patent No. 10,434,228 (“the ’228 Patent”); U.S. Patent No. 10,625,005 (“the ’005 Patent”); U.S. Patent No. 10,722,624 (“the ’624 Patent”); U.S. Patent No. 11,185,619 (“the ’619 Patent”); U.S. Design Patent No. D832,995 (“the ’D995 Patent”); U.S. Design Patent No. D977,625 (“the ’D625 Patent”); and U.S. Patent No. 10,688,229 (“the ’229 patent”) (collectively, the “Asserted Patents”). Elvie denies the remaining allegations of Paragraph 17.

18. The Asserted Patents recognized multiple problems with then-existing systems and methods for pumping milk. For example, as the ’624 Patent explains, “[a]lthough a variety of breast pumps are available, most are awkward and cumbersome, requiring many parts and assemblies and being difficult to transport.” Exhibit 1 at 1:30-32. Manual breast pumps can be “onerous” and “painful” to use. *Id.* at 1:33-34. Some of the available powered breast pumps “require an AC power source to plug into during use,” while other available battery-powered pumps “draw down the battery power fairly rapidly as the motorized pump continuously operates to maintain suction during the milk extraction process.” *Id.* at 1:36-38. Existing pumps had the further disadvantages of being “clearly visible to an observer when the mother is using it” and “expos[ing] the breast of the mother during use.” *Id.* at 1:38-41. As the ’624 Patent explains, “[t]here is a continuing need for a small, portable...wearable breast pump system” that would not expose the breast of the user, and could be “invisible or nearly unnoticeable when worn.” *Id.* at 1:42-46.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of text of the ’624 patent, but the actual and complete disclosure of the ’624 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 18.

19. To address these deficiencies in the art, the Asserted Patents provide a wearable, inconspicuous, convenient pump. In various embodiments, “the system defines a natural breast profile” which would “fit comfortably and conveniently into a bra of a

user and to present a natural look.” Exhibit 1 at 2:5-8. The pumping devices and storage containers of the inventions can be “sized and shaped to be received within a user’s bra.” *Id.* at 2:24-26. “Pumping of milk from a breast can occur without creating a change in a total mass and volume of the breast, pump device and storage container. The storage container can be one or more of flexible, or position around the breast.” *Id.* at 2:26-30.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of text of the ’624 patent, but the actual and complete disclosure of the ’624 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 19.

U.S. Patent No. 10,398,816

20. On September 3, 2019, the USPTO duly and lawfully issued the ’816 Patent, entitled “Breast pump system with flange.” A true and correct copy of the ’816 Patent is attached as Exhibit 2. By assignment, duly recorded with the USPTO, Willow owns all substantial rights to the ’816 Patent, including the right to sue and recover damages for all infringement.

ANSWER: Elvie admits that on its face, the ’812 patent titled “Breast pump system with flange” issued on September 3, 2019. Elvie lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations of Paragraph 20 as pled and denies those allegations on that basis.

21. The ’816 Patent generally relates to a breast pumping system where milk is expressed from the breast under suction, and the milk is moved by the pumping mechanism to a collection container using pressure and all responsive to a controller. *See id.* at Abstract. The ’816 Patent further provides for a portion of the system that contacts the skin, called the flange, designed as a “lower profile component” as compared to the prior art. *Id.* at 20:10-11.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of text of the ’816 patent, but the actual and complete disclosure of the ’816 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 21 that are contrary to the actual and complete disclosure of the ’816 patent.

22. The ’816 Patent recognized a problem with then-existing systems and methods for pumping milk. As the ’816 Patent explains, “[a]lthough a variety of breast pumps are available, most are awkward and cumbersome, requiring many parts and assemblies

and being difficult to transport.” Exhibit 2 at 1:23-25. Manual breast pumps can be “onerous” and “painful” to use. *Id.* at 1:25-27. Some of the available powered breast pumps “require an AC power source to plug into during use,” while other available battery-powered pumps “draw down the battery power fairly rapidly as the motorized pump continuously operates to maintain suction during the milk extraction process.” *Id.* at 1:27-31. Existing pumps had the further disadvantages of being “clearly visible to an observer when the mother is using it” and “expos[ing] the breast of the mother during use.” *Id.* at 1:31-34. In addition, “[m]any existing breast pump systems can cause considerable discomfort to the user over time. One cause of such discomfort is chafing of the nipple against the nipple flange/housing as the nipple stretches and contracts during the pumping session. There is a continuing need for a breast pump system that is more comfortable to the user, even over repeated pumping sessions.” *Id.* at 1:49-55.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of text of the ’816 patent, but the actual and complete disclosure of the ’816 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 22.

23. The ’816 Patent describes specific improvements to then-existing systems and methods for pumping milk. For example, in various embodiments, “the system defines a natural breast profile” which would “fit comfortably and conveniently into a bra of a user and to present a natural look.” *Id.* at 2:14-18. In addition, the claimed system maintains “at least a latch suction level at all times,” which results in a “more secure and persistent seal to the breast and significantly reduce[d] potential for leaks.” *Id.* at 20:3-6. This has several benefits to the user, including “less friction on the side of the nipple against the flange wall, thereby greatly reducing the risk of irritation, skin damage, pain, swelling, etc.” *Id.* at 19:64-67. Additionally, because “the nipple travels less, this allows for the skin attachment member/flange to be designed as a lower profile component, as its length can be shorter...” *Id.* at 20:9-11. This benefit in turn limits the “overall amount of protrusion of the system from the breast to less than that in the prior art...” *Id.* at 20: 13-15.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of text of the ’816 patent, but the actual and complete disclosure of the ’816 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 23.

24. As an example of the improvements in the ’816 Patent over the prior art, Figure 8 provides a flange of an embodiment of the invention, and Figure 9 provides an exemplary prior art flange:

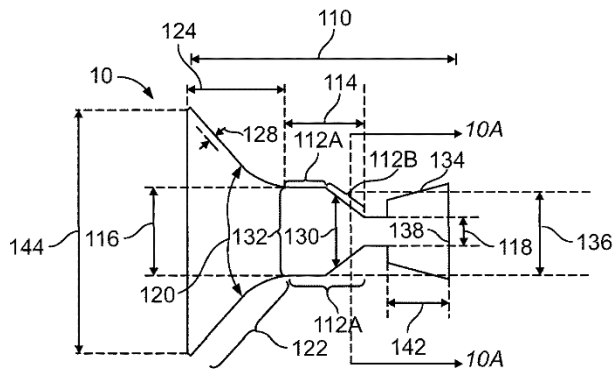


FIG. 8

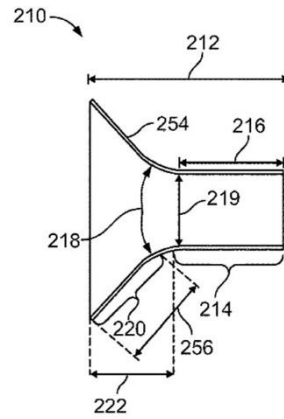


FIG. 9
PRIOR ART

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of figures of the '816 patent, but the actual and complete disclosure of the '816 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 24 that are contrary to the actual and complete disclosure of the '816 patent.

25. The claims of the '816 Patent capture specific technological improvements. For example, Claim 1 of the '816 Patent provides for "a flange attached to the breast pump shell and configured to receive the breast" with a "rigid nipple receiving portion." *Id.*, Claim 1, 50:56-61. Claim 6 of the '816 Patent adds a limitation to a "control loop [] used to adjust a speed of the compression member to vary or maintain the suction pressure." *Id.*, Claim 6, 51:12-16.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of text of the '816 patent, but the actual and complete disclosure of the '816 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 25.

26. The claimed improvements of the '816 Patent, including the ability to maintain suction and the corresponding characteristics of the claimed flange, were not routine, conventional, or well-known. These improvements were advantageous and inventive over the prior art systems that were cumbersome, difficult to transport, inefficient and/or inconvenient to power, and difficult to use discreetly. The '816 Patent recognized the unconventional and advantageous nature of the claimed small, portable, self-powered, energy efficient, wearable breast pump system. *Id.* at 1:35-49. As the '816 Patent explains, these improvements were advantageous and inventive over the prior art systems with less comfortable skin contact portions. The '816 Patent recognized the unconventional and advantageous nature of achieving a shorter protrusion of the system from the breast, by providing improved suction and, in turn,

the claimed flange. The improved systems and methods of the '816 Patent, recited in the claims, provide technological benefits over the prior art.

ANSWER: Denied.

U.S. Patent No. 10,434,228

27. On October 8, 2019, the USPTO duly and lawfully issued the '228 Patent, entitled "Breast pump system and methods." A true and correct copy of the '228 Patent is attached as Exhibit 4. By assignment, duly recorded with the USPTO, Willow owns all substantial rights to the '228 Patent, including the right to sue and recover damages for all infringement.

ANSWER: Elvie admits that on its face, the '228 patent titled "Breast pump system and methods" issued on October 8, 2019. Elvie lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations of Paragraph 27 as pled and denies those allegations on that basis.

28. The '228 Patent generally relates to a breast pumping system where milk is expressed from the breast under suction, and the milk is moved by the pumping mechanism to a collection container using pressure. *See id.* at Abstract.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete summaries of the text of the '228 patent, but the actual and complete disclosure of the '228 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 28 that are contrary to the actual and complete disclosure of the '228 patent.

29. The '228 Patent recognized a problem with then-existing systems and methods for pumping milk. As the '228 Patent explains, "[w]hen a user has completed the pumping phase of extracting milk..., it is useful and efficient to purge as much milk that remains...from the tubing [] and into the milk collection container []." *Id.* at 41:8-11.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of text of the '228 patent, but the actual and complete disclosure of the '228 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 29.

30. The '228 Patent describes specific improvements to then-existing systems and methods for pumping milk. In particular, the '228 Patent provides systems with

numerous methods for avoiding loss of milk after extraction from the breast. For example, Figure 38 illustrates events that may be carried out to perform a purge. *Id.* at 14:37-39. Figures 39A and 39B further provide additional arrangements that may be provided to help prevent loss of milk out of the system.

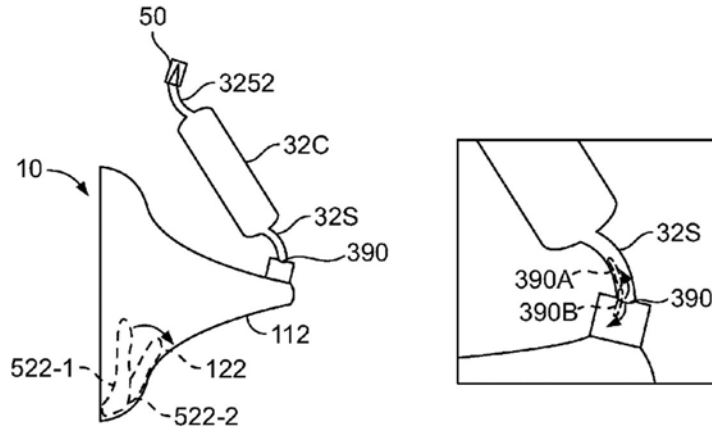


FIG. 39A

FIG. 39B

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of text and figures of the '228 patent, but the actual and complete disclosure of the '228 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 30.

31. The claims of the '228 Patent capture specific technological improvements. For example, Claim 1 provides an automated method of pumping milk, "wherein the milk is pumped from the breast to the collection container upwardly through the milk flow path relative to a bottom of the breast contacting structure." *Id.* at Claim 1, 50:44-47.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of text of the '228 patent, but the actual and complete disclosure of the '228 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 31.

32. The claimed improvements of the '228 Patent were not routine, conventional, or well-known. As the '228 Patent explains, these improvements were advantageous and inventive over the prior art techniques without the provided methods of avoiding milk loss. The '228 Patent recognized the unconventional and advantageous nature of directing the flow of milk upward. The improved systems and methods of the '228 Patent, recited in the claims, provide technological benefits over the prior art.

ANSWER: Denied.

U.S. Patent No. 10,625,005

33. On April 21, 2020, the USPTO duly and lawfully issued the '005 Patent, entitled "Breast pump assembly with remote interface." A true and correct copy of the '005 Patent is attached as Exhibit 5. By assignment, duly recorded with the USPTO, Willow owns all substantial rights to the '005 Patent, including the right to sue and recover damages for all infringement.

ANSWER: Elvie admits that on its face, the '005 patent titled "Breast pump assembly with remote interface" issued on April 21, 2020. Elvie lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations of Paragraph 33 as pled and denies those allegations on that basis.

34. The '005 Patent generally relates to a breast pumping system where milk is expressed from the breast under suction, and the milk is moved by the pumping mechanism to a collection container using pressure. *See id.* at Abstract. The '005 Patent provides for a remote user interface system, including user control functionality. *Id.* at Claim 1, 28:33-34.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete summaries of the text of the '005 patent, but the actual and complete disclosure of the '005 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 34 that are contrary to the actual and complete disclosure of the '005 patent.

35. The '005 Patent recognized a problem with then-existing systems and methods for pumping milk. As the '005 Patent explains, "[t]here is a continuing need for a small, portable, self-powered, energy efficient, wearable breast pump that is easy to use, that mimics natural nursing, and is...nearly unnoticeable when worn." *Id.* at 1:54-58. In particular, it would be desirable to "easily and accurately monitor[] the volume of milk pumped by the system" and to "track milk volume pumped per session." *Id.* at 1:59-67.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of text of the '005 patent, but the actual and complete disclosure of the '005 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 35.

36. The '005 Patent describes specific improvements to then-existing systems and methods for pumping milk. For example, a remote user interface system allows for "at least the session start time, the session end time and total volume of milk extracted

from the breast” to be “stored and tracked.” *Id.* at 25:15-17. Live data and historical data can be treated differently, and be downloaded to an external device during or immediately after a session, or downloaded as multiple session data. *Id.* at 25:27-46. The remote user interface “can also include specific user control functionality, and various related easy to understand displays.” *Id.* at 26:15-16. Figures 30 and 31 provide exemplary aspects of a remote user interface system:

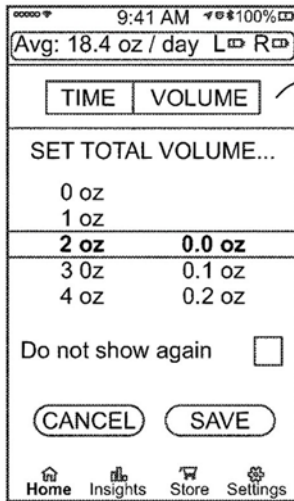


FIG. 30

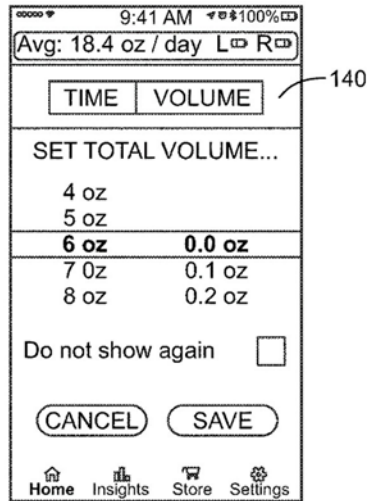


FIG. 31

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of text and figures of the '005 patent, but the actual and complete disclosure of the '005 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 36.

37. The claims of the '005 Patent capture specific technological improvements. For example, Claim 1 is directed to a breast pump with a wireless transmitter, a “language protocol for two-way communication between the breast pump and an external device,” and a “remote user interface including user control functionality” and “an input for the human to adjust the breast pump with the external device.” *Id.* at Claim 1, 28:25-41.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of text of the '005 patent, but the actual and complete disclosure of the '005 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 37.

38. The claimed improvements of the '005 Patent were not routine, conventional, or well-known. As the '005 Patent explains, these improvements were advantageous and inventive over the prior art techniques that did not allow for a remote user interface system. The '005 Patent recognized the unconventional and advantageous nature of a wireless system that empowered nursing mothers to control the operation of the breast

pump through an external device. The improved systems and methods of the '005 Patent, recited in the claims, provide technological benefits over the prior art.

ANSWER: Denied.

U.S. Patent No. 10,772,624

39. On July 28, 2020, the USPTO duly and lawfully issued the '624 Patent, entitled "Breast pump assembly with breast adapter." A true and correct copy of the '624 Patent is attached as Exhibit 1. By assignment, duly recorded with the USPTO, Willow owns all substantial rights to the '624 Patent, including the right to sue and recover damages for all infringement.

ANSWER: Elvie admits that on its face, the '624 patent titled "Breast pump assembly with breast adapter" issued on July 28, 2020. Elvie lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations of Paragraph 39 as pled and denies those allegations on that basis.

40. The '624 Patent generally relates to a breast milk pump that uses a pumping mechanism to expulse milk from a breast and to then store the milk in a milk collection container. The entire assembly may include both the pump and the storage container. *See id.* at Abstract.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete summaries of the text of the '624 patent, but the actual and complete disclosure of the '624 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 40 that are contrary to the actual and complete disclosure of the '624 patent.

41. The '624 Patent provides for various embodiments of the breast pumping system. In one example, in order to achieve the desired milk expression, "suction applied to the breast for expression of milk involves a first suction level, and during expulsing, a second suction level is maintained against the breast, the second suction level being lower than the first suction level." *Id.* at 1:67-2:4.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of text of the '624 patent, but the actual and complete disclosure of the '624 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 41 that are contrary to the actual and complete disclosure of the '624 patent.

42. As the '624 Patent explains, “[a]lthough a variety of breast pumps are available, most are awkward and cumbersome, requiring many parts and assemblies and being difficult to transport.” *Id.* at 1:30-32. Manual breast pumps can be “onerous” and “painful” to use. *Id.* at 1:32-34. Some of the available powered breast pumps “require an AC power source to plug into during use,” while other available battery-powered pumps “draw down the battery power fairly rapidly as the motorized pump continuously operates to maintain suction during the milk extraction process.” *Id.* at 1:33-37. Existing pumps had the further disadvantages of being “clearly visible to an observer when the mother is using it” and “expos[ing] the breast of the mother during use.” *Id.* at 1:37-40.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of text of the '624 patent, but the actual and complete disclosure of the '624 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 42.

43. The '624 Patent describes specific improvements to then-existing systems and methods for pumping milk. For example, in various embodiments, “the system defines a natural breast profile” which would “fit comfortably and conveniently into a bra of a user and to present a natural look.” *Id.* at 2:5-8. Another approach could include “outputting at least one of operational and/or sensed parameters, and modifying at least one operational setting based upon” the same. *Id.* at 3:47-49. An operational setting could include “suction level setting, suction waveform definition, extraction phase time, threshold milk volume estimate per extraction phase expulsion, pressure, rest phase time, heating temperatures, heating times, vibration frequency and vibration times.” *Id.* at 3:50-55. The '624 Patent provides a system or method that “can further perform in real-time, or as a feedback loop.” *Id.* at 3:49-50.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of text of the '624 patent, but the actual and complete disclosure of the '624 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 43.

44. The claims of the '624 Patent capture specific technological improvements. For example, Claim 1 is directed to an “automated system for controlling pumping cycles” including a “sensor which detects when the milk collection container is full” and a controller that “automatically changes application of suction” based on the phase of milk expression from the user. *Id.* at Claim 1, 53:10-54:8.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of text of the '624 patent, but the actual and complete disclosure of the '624 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 44.

45. The claimed improvements of the '624 Patent were not routine, conventional, or well-known. As the '624 Patent explains, these improvements were advantageous and inventive over the prior art systems that were cumbersome, difficult to transport, inefficient and/or inconvenient to power, and difficult to use discreetly. The '624 Patent recognized the unconventional and advantageous nature of the claimed small, portable, self-powered, energy efficient, wearable breast pump system. *Id.* at 1:42-46. The claims recited systems with features including control of the pumping cycle. *Id.* at Claim 1, 53:10-54:8. The improved systems and methods of the '624 Patent, recited in the claims, provide technological benefits over the prior art.

ANSWER: Denied.

U.S. Patent No. 11,185,619

46. On November 30, 2021, the USPTO duly and lawfully issued the '619 Patent, entitled "Breast pump system with pressure sensor." A true and correct copy of the '619 Patent is attached as Exhibit 6. By assignment, duly recorded with the USPTO, Willow owns all substantial rights to the '619 Patent, including the right to sue and recover damages for all infringement.

ANSWER: Elvie admits that on its face, the '619 patent titled "Breast pump system with pressure sensor" issued on November 30, 2021. Elvie lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations of Paragraph 46 as pled and denies those allegations on that basis.

47. The '619 Patent generally relates to a breast pumping system where milk is expressed from the breast under suction, and the milk is moved from the pumping mechanism to a collection container using pressure and all responsive to a controller. *See id.* at Abstract. The system of the '619 Patent further includes a wireless transmitter and a pressure sensor.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete summaries of the text of the '619 patent, but the actual and complete disclosure of the '619 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 47 that are contrary to the actual and complete disclosure of the '619 patent.

48. The '619 Patent recognized a problem with then-existing systems and methods for pumping milk. As the '619 Patent explains, "[a]lthough a variety of breast pumps are available, most are awkward and cumbersome, requiring many parts and assemblies and being difficult to transport." *Id.* at 1:25-27. Manual breast pumps can be "onerous" and "painful" to use. *Id.* at 1:27-29. Some of the available powered breast

pumps “require an AC power source to plug into during use,” while other available battery-powered pumps “draw down the battery power fairly rapidly as the motorized pump continuously operates to maintain suction during the milk extraction process.” *Id.* at 1:30-33. Existing pumps had the further disadvantages of being “clearly visible to an observer when the mother is using it” and “expos[ing] the breast of the mother during use.” *Id.* at 1:33-36. The ’619 Patent explained the desirability of “a breast pump system that easily and accurately monitors the volume of milk pumped by the system,” and that it “would also be desirable to track milk volume pumped by the system.” *Id.* at 1:43-49.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of text of the ’619 patent, but the actual and complete disclosure of the ’619 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 48.

49. The ’619 Patent describes specific improvements to then-existing systems and methods for pumping milk. For example, the system of the ’619 Patent provides for a sensor “used to provide feedback to the controller” to control the pumping cycles. *Id.* at 29:42-48. With a sensor present, “it is possible to derive/calculate approximately the volume of milk produced during a pumping session as well as understand the flow-rate at any particular time in a pumping session.” *Id.* at 30:8-14. The ’619 Patent further provides for wireless connection between the controller of the pumping system and an external computer, such as a smartphone or laptop. *Id.* at 35:66-36:5. Through this connection, the system of the ’619 Patent can compile information related to milk extraction and collection. *Id.* at 37:25-32; 38:21-39.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of text of the ’619 patent, but the actual and complete disclosure of the ’619 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 49.

50. The claims of the ’619 Patent capture specific technological improvements. For example, Claim 1 is directed to a system that includes a vacuum pumping mechanism, a wireless transmitter, and a non-contact pressure sensor that measures vacuum levels within the automated system. *Id.* at Claim 1, 50:44-61.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete summaries of the text of the ’619 patent, but the actual and complete disclosure of the ’619 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 50 that are contrary to the actual and complete disclosure of the ’619 patent.

51. The claimed improvements of the ’619 Patent were not routine, conventional, or well-

known. As the '619 Patent explains, these improvements were advantageous and inventive over the prior art techniques that did not meet the needs of nursing mothers. The '619 Patent recognized the unconventional and advantageous nature of using a non-contact sensor to monitor the process of extraction and collection, and a wireless transmitter to convey information related to extracted and collected milk. The improved systems and methods of the '619 Patent, recited in the claims, provide technological benefits over the prior art.

ANSWER: Denied.

U.S. Design Patent No. D832,995

52. On November 6, 2018, the USPTO duly and lawfully issued the 'D995 Patent, entitled "Breast pump." A true and correct copy of the 'D995 Patent is attached as Exhibit 7. By assignment, duly recorded with the USPTO, Willow owns all substantial rights to the 'D995 Patent, including the right to sue and recover damages for all infringement.

ANSWER: Elvie admits that on its face, the 'D995 patent titled "Breast pump" issued on November 6, 2018. Elvie lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations of Paragraph 52 as pled and denies those allegations on that basis.

53. The 'D995 Patent is an ornamental design for a breast pump, as shown and described. Figure 1 provides an isometric view of the claimed breast pump:

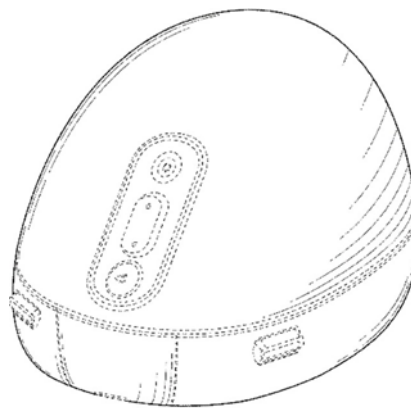


FIG. 1

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of a figure of the 'D995 patent, but the actual and complete disclosure of the 'D995 patent speaks

for itself and is controlling. Elvie denies the remaining allegations of Paragraph 53 that are contrary to the actual and complete disclosure of the 'D995 patent.

U.S. Design Patent No. D977,625

54. On February 7, 2023, the USPTO duly and lawfully issued the 'D625 Patent, entitled "Breast pump." A true and correct copy of the 'D625 Patent is attached as Exhibit 8. By assignment, duly recorded with the USPTO, Willow owns all substantial rights to the 'D625 Patent, including the right to sue and recover damages for all infringement.

ANSWER: Elvie admits that on its face, the 'D625 patent titled "Breast pump" issued on February 7, 2023. Elvie lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations of Paragraph 54 as pled and denies those allegations on that basis.

55. The 'D625 Patent is an ornamental design for a breast pump, as shown and described. Figure 1 provides an isometric view of the claimed breast pump:

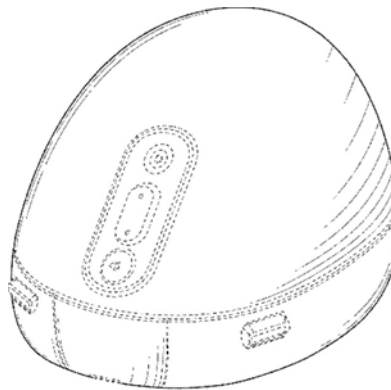


FIG. 1

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of a figure of the 'D625 patent, but the actual and complete disclosure of the 'D625 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 55 that are contrary to the actual and complete disclosure of the 'D625 patent.

U.S. Patent No. 10,688,229

56. On June 23, 2020, the United States Patent Office ("USPTO") duly and lawfully issued the '229 Patent, entitled "Breast pump system and methods." A true and

correct copy of the '229 Patent is attached as Exhibit 16. By assignment, duly recorded with the USPTO, Willow owns all substantial rights to the '229 Patent, including the right to sue and recover damages for all infringement.

ANSWER: Elvie admits that on its face, the '229 patent entitled “Breast pump system and methods” issued on June 23, 2020. Elvie lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations of Paragraph 56 as pled and denies those allegations on that basis.

57. The '229 Patent generally relates to a breast pumping system where milk is expressed from the breast under suction, and the milk is moved from the pumping mechanism to a collection container. *See id.* at Abstract.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete summaries of the text of the '229 patent, but the actual and complete disclosure of the '229 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 57 that are contrary to the actual and complete disclosure of the '229 patent.

58. The '229 Patent provides for various embodiments of the breast pumping system, including systems where “[e]xpulsion of expressed milk can be achieved by the application of a relative positive pressure to a portion of the conduit.” *Id.* at 1:64-66. In one example, in order to achieve the desired milk expression, “suction applied to the breast for expression of milk involves a first suction level, and during expulsing, a second suction level is maintained against the breast, the second suction level being lower than the first suction level.” *Id.* at 1:66-2:3

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of text of the '229 patent, but the actual and complete disclosure of the '229 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 58 that are contrary to the actual and complete disclosure of the '229 patent.

59. The '229 Patent recognized multiple problems with then-existing systems and methods for pumping milk. As the '229 Patent explains, “[a]lthough a variety of breast pumps are available, most are awkward and cumbersome, requiring many parts and assemblies and being difficult to transport.” *Id.* at 1:29-31. Manual breast pumps can be “onerous” and “painful” to use. *Id.* at 1:31-33. Some of the available powered breast pumps “require an AC power source to plug into during use,” while other available battery-powered pumps “draw down the battery power fairly rapidly as the

motorized pump continuously operates to maintain suction during the milk extraction process.” *Id.* at 1:33-37. Existing pumps had the further disadvantages of being “clearly visible to an observer when the mother is using it” and “expos[ing] the breast of the mother during use.” *Id.* at 1:37-40.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of text of the ’229 patent, but the actual and complete disclosure of the ’229 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 59.

60. The ’229 Patent describes specific improvements to then-existing systems and methods for pumping milk. For example, in various embodiments, “the system defines a natural breast profile” which would “fit comfortably and conveniently into a bra of a user and to present a natural look.” *Id.* at 2:4-7. Another approach could include “outputting at least one of operational and/or sensed parameters, and modifying at least one operational setting based upon” the same. *Id.* at 3:46-48. An operational setting could include “suction level setting, suction waveform definition, extraction phase time, threshold milk volume estimate per extraction phase expulsion, pressure, rest phase time, heating temperatures, heating times, vibration frequency and vibration times.” *Id.* at 3:50-55. The ’229 Patent provides a system or method that “can further perform in real-time, or as a feedback loop.” *Id.* at 3:49-50.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of text of the ’229 patent, but the actual and complete disclosure of the ’229 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 60.

61. Figure 65 of the ’229 Patent provides an illustration of one embodiment of the claimed breast pump system, in use inside the user’s bra:

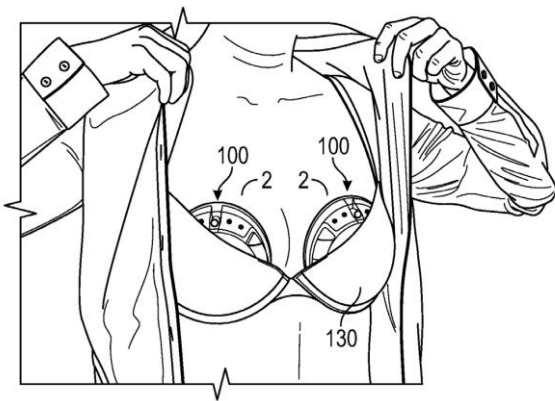


FIG. 65

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete selections of text and figures of the '229 patent, but the actual and complete disclosure of the '229 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 61.

62. The claims of the '229 Patent capture specific technological improvements. For example, Claim 1 is directed to a “wearable, portable self-powered breast pump system” including an adapter, a pump, and collection container, all “collectively sized and shaped to fit within a user’s bra.” *Id.* at Claim 1, 53:11-23.

ANSWER: Elvie admits that Plaintiff purports to present certain incomplete summaries of the text of the '229 patent, but the actual and complete disclosure of the '229 patent speaks for itself and is controlling. Elvie denies the remaining allegations of Paragraph 62 that are contrary to the actual and complete disclosure of the '229 patent.

63. The claimed improvements of the '229 Patent were not routine, conventional, or well-known. As the '229 Patent explains, these improvement were advantageous and inventive over the prior art systems that were cumbersome, difficult to transport, inefficient and/or inconvenient to power, and difficult to use discreetly. The '229 Patent recognized the unconventional and advantageous nature of the claimed small, portable, self-powered, energy efficient, wearable breast pump system. *Id.* at 1:41-45. The improved systems and methods of the '229 Patent, recited in the claims, provide technological benefits over the prior art.

ANSWER: Denied.

THE ACCUSED PRODUCTS

64. Elvie infringed, and continues to directly infringe, each of the Asserted Patents in violation of 35 U.S.C. § 271(a) by making, using, selling, offering for sale in the United States, and/or importing into the United States, without authorization, products that practice the various claims of the Asserted Patents literally or under the doctrine of equivalents. Those products include, for example, the Elvie Pump and any mobile applications designed for use in conjunction with the Elvie Pump (collectively, the “Accused Products”).

ANSWER: Denied.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 10,398,816

65. Willow incorporates by reference the proceeding paragraphs as if fully set forth herein.

ANSWER: Elvie incorporates by reference its responses to paragraphs 1 through 64.

66. Elvie has directly infringed, and continues to directly infringe, the '816 Patent in violation of 35 U.S.C. § 271(a) by making, using, selling, offering for sale in the United States, and/or importing into the United States, without authorization, the Accused Products that practice various claims of the '816 Patent literally or under the doctrine of equivalents.

ANSWER: Denied.

67. Willow has complied with all statutory requirements, including the requirements of 35 U.S.C. § 287, to pursue and recover for any infringement of the '816 Patent.

ANSWER: Elvie lacks sufficient knowledge and information to form a belief as to the truth of the allegations of Paragraph 67 as pled and denies those allegations on that basis. Elvie further denies that Willow's virtual patent marking provides sufficient notice to the public of each patent covering each of Willow's products.

68. As a non-limiting example, the Accused Products meet every element of at least Claim 1 of the '816 Patent literally or under the doctrine of equivalents. Claim 1 recites:

[preamble] An automated breast pump system for pumping milk from a breast of a user, comprising:

[1a] a breast pump configured to fit within a bra, the breast pump including: [1b] a breast pump shell housing a milk flow path;

[1c] a pumping mechanism, the pumping mechanism contained completely within the breast pump shell;

[1d] a fluid container configured to directly engage and be supported by the breast pump shell, wherein the fluid container is connected to the milk flow path;

[1e] a flange attached to the breast pump shell and configured to receive the breast, the flange including a rigid nipple receiving portion and a bottom portion, the bottom portion configured below the nipple receiving portion during use, the nipple receiving portion including a proximal end defining an opening; and

[1f] an external computer that automatically tracks pumping and communicates with the pumping mechanism;

[1g] wherein the pumping mechanism is associated with the rigid nipple receiving portion and the pumping mechanism is configured to create a suction force from the rigid nipple receiving portion, the suction force and the milk flow path both being directed generally upward relative to the bottom portion of the flange.

ANSWER: Denied.

69. Exhibit 9 to this Complaint is a claim chart showing a non-limiting example of how Elvie's breast pumps and applications satisfy Claim 1 literally or under the doctrine of equivalents. The components and functionality in this chart are representative of the components and functionality present in all Accused Products. Elvie thus directly infringed and continues to directly infringe each limitation of at least Claim 1 of the '816 Patent by making, using, selling, offering for sale in the United States, and/or importing into the United States, without authorization, the Accused Products.

ANSWER: Denied.

70. On information and belief, Elvie has known about the '816 Patent since at least its issuance on September 3, 2019. Elvie's knowledge is due to at least (1) its presence in the breast pump market and status as Willow's competitor; (2) its monitoring of competitors' patent applications and issued patents; (3) its claim that its Elvie Pump is substantially equivalent to the Willow Pump during FDA pre-market proceedings and (4) Willow's substantial and continuous practice of providing constructive notice of its patents on its website. On information and belief, competitors such as Elvie generally monitor the patent applications, issued patents, and litigation activity of one another.

ANSWER: Denied.

71. For example, the '816 Patent was cited during the prosecution of Elvie's patent applications. *See* Exs. 10, 11 (U.S. Patent Nos. 11,413,380 and D954,933, assigned to Elvie, citing the '816 Patent). Accordingly, Elvie had pre-suit knowledge of the '816 Patent at least through its prosecution activities.

ANSWER: Elvie admits that the '816 patent appears on the face of U.S. Patent Nos. 11,413,380 and D954,933 under "References Cited." Elvie denies the remaining allegations of Paragraph 71.

72. In the alternative, at least as of the filing date of this lawsuit, Elvie has had knowledge of the '816 Patent and knowledge of how Elvie and third parties infringe that patent.

ANSWER: Denied.

73. Elvie's knowledge of the '816 Patent is sufficient to satisfy the knowledge element for induced, contributory, and willful infringement.

ANSWER: Denied.

74. Elvie indirectly infringes at least Claim 1 of the '816 Patent in violation of 35 U.S.C. § 271(b) by taking active steps to encourage and facilitate direct infringement by third parties, including users, partners, affiliates, subsidiaries, and service providers, in the United States with knowledge and the specific intent that its efforts would result in the direct infringement of the '816 Patent. For example, Elvie actively induces infringement of the '816 Patent by designing, manufacturing, selling, or distributing the Accused Products and then training its customers and users on the use of those products and the accompanying mobile applications, including through the creation and dissemination of supporting materials, videos, instructions, product manuals, and technical information. <https://www.elvie.com/en-us/support/elvie-pump/using-elvie-pump-app/can-i-use-elvie-pump-without-the-app>. In addition, Elvie actively induces infringement of the '816 Patent by instructing, encouraging, or requiring its subsidiaries and affiliates to make, use, sell, offer for sale in the United States, and import into the United States, without authorization, the Accused Products that practice various claims of the '816 Patent, such as the Elvie Pump that is used in combination with the corresponding mobile applications. Further, Elvie actively induces infringement of the '816 Patent through the creation and dissemination of promotional and marketing materials. <https://www.youtube.com/watch?v=EXumEnA5qAw&t=95s>. Elvie's active inducement is done with the knowledge and the specific intent that its efforts would result in the direct infringement of the '816 Patent.

ANSWER: Denied.

75. Elvie also is liable for contributory infringement of the '816 Patent under 35 U.S.C. § 271(c) by selling or offering for sale the Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) in the United States and importing the Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) into the United States with knowledge that they are especially designed or adapted to operate in a manner that infringes the '816 Patent and are not a staple article or commodity of commerce suitable for substantial non-infringing use. Elvie contributes to infringement of the '816 Patent by, inter alia, promotion, and/or sales of the infringing Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) to third parties.

ANSWER: Denied.

76. Elvie's infringement of the '816 Patent has been and continues to be willful. As described above, Elvie has had knowledge of the '816 Patent at least since its issuance on September 3, 2019. On its website, Willow has provided substantial and continuous notice to infringers such as Elvie regarding the Asserted Patents, and Willow has included in such notice an identification of Willow products that practice the Asserted Patents. Thus, as one of Willow's primary competitors, Elvie had actual knowledge of the '816 Patent or was willfully blind to its existence. In the alternative, Elvie's infringement has been willful at least since the filing date of this lawsuit.

because it has deliberately continued to infringe the '816 Patent despite knowing of the patent and how Elvie infringes. Further, Willow has deliberately continued to encourage others' infringement of the '816 Patent, including by continuing to disseminate its marketing and technical materials to customers.

ANSWER: Denied.

77. Elvie's acts of infringement have injured and damaged Willow and will continue to injure and damage Willow. Willow is therefore entitled to recover from Elvie the damages it has sustained as a result of Elvie's wrongful and continued acts in an amount to be proven at trial.

ANSWER: Denied.

78. Elvie's infringement has damaged and will continue to damage Willow irreparably, and Willow has no adequate remedy at law for its injuries. In addition to actual damages, Willow is entitled to a permanent injunction enjoining Elvie from infringing the '816 Patent.

ANSWER: Denied.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 10,434,228

79. Willow incorporates by reference the proceeding paragraphs as if fully set forth herein.

ANSWER: Elvie incorporates by reference its responses to paragraphs 1 through 78.

80. Elvie has directly infringed, and continues to directly infringe, the '228 Patent in violation of 35 U.S.C. § 271(a) by making, using, selling, offering for sale in the United States, and/or importing into the United States, without authorization, the Accused Products that practice various claims of the '228 Patent literally or under the doctrine of equivalents.

ANSWER: Denied.

81. Willow has complied with all statutory requirements, including the requirements of 35 U.S.C. § 287, to pursue and recover for any infringement of the '228 Patent.

ANSWER: Elvie lacks sufficient knowledge and information to form a belief as to the truth of the allegations of Paragraph 81 as pled and denies those allegations on that basis. Elvie further denies that Willow's virtual patent marking provides sufficient notice to the public of each patent covering each of Willow's products.

82. As a non-limiting example, the Accused Products meet every element of at least Claim 1 of the '228 Patent literally or under the doctrine of equivalents. Claim 1 recites:

[preamble] An automated method of pumping milk from a breast, the method comprising:

[1a] providing a breast pump system configured to fit within a bra, the breast pump system including a breast pump housing, a breast contacting structure, a milk flow path, and a collection container;

[1b] the milk flow path and the collection container contained within the breast pump housing;

[1c] forming a seal between the breast pump system and the breast; and

[1d] pumping milk expressed from the breast to the collection container;

[1e] wherein the milk is pumped from the breast to the collection container upwardly through the milk flow path relative to a bottom of the breast contacting structure.

ANSWER: Denied.

83. Exhibit 12 to this Complaint is a claim chart showing a non-limiting example of how Elvie's breast pumps and applications satisfy Claim 1 literally or under the doctrine of equivalents. The components and functionality in this chart are representative of the components and functionality present in all Accused Products. Elvie thus directly infringed and continues to directly infringe each limitation of at least Claim 1 of the '228 Patent by making, using, selling, offering for sale in the United States, and/or importing into the United States, without authorization, the Accused Products.

ANSWER: Denied.

84. On information and belief, Elvie has known about the '228 Patent since at least its issuance on October 8, 2019. Elvie's knowledge is due to at least (1) its presence in the breast pump market and status as Willow's competitor; (2) its monitoring of competitors' patent applications and issued patents; (3) its claim that its Elvie Pump is substantially equivalent to the Willow Pump during FDA pre-market proceedings; and (4) Willow's substantial and continuous practice of providing constructive notice of its patents on its website. On information and belief, competitors such as Elvie generally monitor the patent applications, issued patents, and litigation activity of one another.

ANSWER: Denied.

85. For example, the '228 Patent was cited during the prosecution of one or more of Elvie's patent applications. *See* Ex. 10 (U.S. Patent No. 11,413,380, assigned to

Elvie, citing U.S. Pat. App. Pub. No. 2018/0021490—the child application of the ’228 Patent). Accordingly, Elvie had pre-suit knowledge of the ’228 Patent at least through its prosecution activities.

ANSWER: Elvie admits that U.S. Patent Publication No. 2018/0021490 appears on the face of U.S. Patent No. 11,413,380 under “References Cited.” Elvie specifically denies that the citation of U.S. Patent Publication No. 2018/0021490 is equivalent to knowledge of the issued ’228 patent. Elvie denies the remaining allegations of Paragraph 85.

86. In the alternative, at least as of the filing date of this lawsuit, Elvie has had knowledge of the ’228 Patent and knowledge of how Elvie and third parties infringe that patent.

ANSWER: Denied.

87. Elvie’s knowledge of the ’228 Patent is sufficient to satisfy the knowledge element for induced, contributory, and willful infringement.

ANSWER: Denied.

88. Elvie indirectly infringes at least Claim 1 of the ’228 Patent in violation of 35 U.S.C. § 271(b) by taking active steps to encourage and facilitate direct infringement by third parties, including users, partners, affiliates, subsidiaries, and service providers, in the United States with knowledge and the specific intent that its efforts would result in the direct infringement of the ’228 Patent. For example, Elvie actively induces infringement of the ’228 Patent by designing, manufacturing, selling, or distributing the Accused Products and then training its customers and users on the use of those products and the accompanying mobile applications, including through the creation and dissemination of supporting materials, videos, instructions, product manuals, and technical information. <https://www.elvie.com/en-us/support/elvie-pump/using-elvie-pump-app/can-i-use-elvie-pump-without-the-app>. In addition, Elvie actively induces infringement of the ’228 Patent by instructing, encouraging, or requiring its subsidiaries and affiliates to make, use, sell, offer for sale in the United States, and import into the United States, without authorization, the Accused Products that practice various claims of the ’228 Patent, such as the Elvie Pump that is used in combination with the corresponding mobile applications. Further, Elvie actively induces infringement of the ’228 Patent through the creation and dissemination of promotional and marketing materials. <https://www.youtube.com/watch?v=EXumEnA5qAw&t=95s>. Elvie’s active inducement is done with the knowledge and the specific intent that its efforts would result in the direct infringement of the ’228 Patent.

ANSWER: Denied.

89. Elvie also is liable for contributory infringement of the ’228 Patent under 35 U.S.C §

271(c) by selling or offering for sale the Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) in the United States and importing the Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) into the United States with knowledge that they are especially designed or adapted to operate in a manner that infringes the '228 Patent and are not a staple article or commodity of commerce suitable for substantial non-infringing use. Elvie contributes to infringement of the '228 Patent by, inter alia, promotion, and/or sales of the infringing Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) to third parties.

ANSWER: Denied.

90. Elvie's infringement of the '228 Patent has been and continues to be willful. As described above, Elvie has had knowledge of the '228 Patent at least since its issuance on October 8, 2019. On its website, Willow has provided substantial and continuous notice to infringers such as Elvie regarding the Asserted Patents, and Willow has included in such notice an identification of Willow products that practice the Asserted Patents. Thus, as one of Willow's primary competitors, Elvie had actual knowledge of the '228 Patent or was willfully blind to its existence. In the alternative, Elvie's infringement has been willful at least since the filing date of this lawsuit because it has deliberately continued to infringe the '228 Patent despite knowing of the patent and how Elvie infringes. Further, Willow has deliberately continued to encourage others' infringement of the '228 Patent, including by continuing to disseminate its marketing and technical materials to customers.

ANSWER: Denied.

91. Elvie's acts of infringement have injured and damaged Willow and will continue to injure and damage Willow. Willow is therefore entitled to recover from Elvie the damages it has sustained as a result of Elvie's wrongful and continued acts in an amount to be proven at trial.

ANSWER: Denied.

92. Elvie's infringement has damaged and will continue to damage Willow irreparably, and Willow has no adequate remedy at law for its injuries. In addition to actual damages, Willow is entitled to a permanent injunction enjoining Elvie from infringing the '228 Patent.

ANSWER: Denied.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 10,625,005

93. Willow incorporates by reference the proceeding paragraphs as if fully set forth herein.

ANSWER: Elvie incorporates by reference its responses to paragraphs 1 through 92.

94. Elvie has directly infringed, and continues to directly infringe, the '005 Patent in violation of 35 U.S.C. § 271(a) by making, using, selling, offering for sale in the United States, and/or importing into the United States, without authorization, the Accused Products that practice various claims of the '005 Patent literally or under the doctrine of equivalents.

ANSWER: Denied.

95. Willow has complied with all statutory requirements, including the requirements of 35 U.S.C. § 287, to pursue and recover for any infringement of the '005 Patent.

ANSWER: Elvie lacks sufficient knowledge and information to form a belief as to the truth of the allegations of Paragraph 95 as pled and denies those allegations on that basis. Elvie further denies that Willow's virtual patent marking provides sufficient notice to the public of each patent covering each of Willow's products.

96. As a non-limiting example, the Accused Products meet every element of at least Claim 1 of the '005 Patent literally or under the doctrine of equivalents. Claim 1 recites:

[preamble] An automated system for controlling pumping cycles to pump milk from a human breast, the system comprising:

[1a] a breast pump configured to fit within a bra, the breast pump including:

[1b] a chassis;

[1c] an outer shell attached to the chassis;

[1d] a pump mechanism attached to the chassis between the outer shell and chassis;

[1e] a battery contained between the outer shell and chassis;

[1f] a circuit board contained between the outer shell and chassis;

[1g] a sensor electrically connected to the circuit board;

[1h] a removeable breast contacting structure configured to contact and form a seal with the breast, the breast contacting structure including a nipple receiving portion below the pump mechanism; and

[1i] a milk collection container;

[1j] wherein when the removable breast contacting structure is removed, the pump mechanism, battery and circuit board are positioned between the outer shell and the chassis;

[1k] wherein the pump mechanism comprises two drivers that displace a flexible member to generate vacuum pressure in the nipple receiving portion;

[1l] wherein the system further comprises a wireless transmitter transmitting a Bluetooth Low Energy signal containing milk volume collected data;

[1m] wherein the system further comprises a chip tracking usage sessions of the breast pump;

[1n] wherein the system further comprises a language protocol for two-way communication between the breast pump and an external device;

[1o] wherein the system further comprises a remote user interface including user control functionality;

[1p] wherein the system further comprises an internal pump memory within a chip and the wireless transmitter transmits pumped milk volume to the external device which displays the pumped milk volume of each breast;

[1q] wherein the remote user interface has an input for the human to adjust the breast pump with the external device.

ANSWER: Denied.

97. Exhibit 13 to this Complaint is a claim chart showing a non-limiting example of how Elvie's breast pumps and applications satisfy Claim 1 literally or under the doctrine of equivalents. The components and functionality in this chart are representative of the components and functionality present in all Accused Products. Elvie thus directly infringed and continues to directly infringe each limitation of at least Claim 1 of the '005 Patent by making, using, selling, offering for sale in the United States, and/or importing into the United States, without authorization, the Accused Products.

ANSWER: Denied.

98. On information and belief, Elvie has known about the '005 Patent since at least its issuance on April 21, 2020. Elvie's knowledge is due to at least (1) its presence in the breast pump market and status as Willow's competitor; (2) its monitoring of competitors' patent applications and issued patents; (3) its claim that its Elvie Pump is substantially equivalent to the Willow Pump during FDA pre-market proceedings; and (4) Willow's substantial and continuous practice of providing constructive notice of its patents on its website. On information and belief, competitors such as Elvie generally monitor the patent applications, issued patents, and litigation activity of one

another.

ANSWER: Denied.

99. For example, the '005 Patent was cited during the prosecution of Elvie's patent applications. *See* Exs. 10, 11 (U.S. Patent Nos. 11,413,380 and D954,933, assigned to Elvie, citing the '005 Patent). Accordingly, Elvie had pre-suit knowledge of the '005 Patent at least through its prosecution activities.

ANSWER: Elvie admits that the '005 patent appears on the face of U.S. Patent Nos. 11,413,380 and D954,933 under "References Cited." Elvie denies the remaining allegations of Paragraph 99.

100. In the alternative, at least as of the filing date of this lawsuit, Elvie has had knowledge of the '005 Patent and knowledge of how Elvie and third parties infringe that patent.

ANSWER: Denied.

101. Elvie's knowledge of the '005 Patent is sufficient to satisfy the knowledge element for induced, contributory, and willful infringement.

ANSWER: Denied.

102. Elvie indirectly infringes at least Claim 1 of the '005 Patent in violation of 35 U.S.C. § 271(b) by taking active steps to encourage and facilitate direct infringement by third parties, including users, partners, affiliates, subsidiaries, and service providers, in the United States with knowledge and the specific intent that its efforts would result in the direct infringement of the '005 Patent. For example, Elvie actively induces infringement of the '005 Patent by designing, manufacturing, selling, or distributing the Accused Products and then training its customers and users on the use of those products and the accompanying mobile applications, including through the creation and dissemination of supporting materials, videos, instructions, product manuals, and technical information. <https://www.elvie.com/en-us/support/elvie-pump/using-elvie-pump-app/can-i-use-elvie-pump-without-the-app>. In addition, Elvie actively induces infringement of the '005 Patent by instructing, encouraging, or requiring its subsidiaries and affiliates to make, use, sell, offer for sale in the United States, and import into the United States, without authorization, the Accused Products that practice various claims of the '005 Patent, such as the Elvie Pump that is used in combination with the corresponding mobile applications. Further, Elvie actively induces infringement of the '005 Patent through the creation and dissemination of promotional and marketing materials. <https://www.youtube.com/watch?v=EXumEnA5qAw&t=95s>. Elvie's active inducement is done with the knowledge and the specific intent that its efforts would result in the direct infringement of the '005 Patent.

ANSWER: Denied.

103. Elvie also is liable for contributory infringement of the '005 Patent under 35 U.S.C § 271(c) by selling or offering for sale the Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) in the United States and importing the Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) into the United States with knowledge that they are especially designed or adapted to operate in a manner that infringes the '005 Patent and are not a staple article or commodity of commerce suitable for substantial non-infringing use. Elvie contributes to infringement of the '005 Patent by, inter alia, promotion, and/or sales of the infringing Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) to third parties.

ANSWER: Denied.

104. Elvie's infringement of the '005 Patent has been and continues to be willful. As described above, Elvie has had knowledge of the '005 Patent at least since its issuance on April 21, 2020. On its website, Willow has provided substantial and continuous notice to infringers such as Elvie regarding the Asserted Patents, and Willow has included in such notice an identification of Willow products that practice the Asserted Patents. Thus, as one of Willow's primary competitors, Elvie had actual knowledge of the '005 Patent or was willfully blind to its existence. In the alternative, Elvie's infringement has been willful at least since the filing date of this lawsuit because it has deliberately continued to infringe the '005 Patent despite knowing of the patent and how Elvie infringes. Further, Willow has deliberately continued to encourage others' infringement of the '005 Patent, including by continuing to disseminate its marketing and technical materials to customers.

ANSWER: Denied.

105. Elvie's acts of infringement have injured and damaged Willow and will continue to injure and damage Willow. Willow is therefore entitled to recover from Elvie the damages it has sustained as a result of Elvie's wrongful and continued acts in an amount to be proven at trial.

ANSWER: Denied.

106. Elvie's infringement has damaged and will continue to damage Willow irreparably, and Willow has no adequate remedy at law for its injuries. In addition to actual damages, Willow is entitled to a permanent injunction enjoining Elvie from infringing the '005 Patent.

ANSWER: Denied.

COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 10,722,624

107. Willow incorporates by reference the proceeding paragraphs as if fully set forth herein.

ANSWER: Elvie incorporates by reference its responses to paragraphs 1 through 106.

108. Elvie has directly infringed, and continues to directly infringe, the '624 Patent in violation of 35 U.S.C. § 271(a) by making, using, selling, offering for sale in the United States, and/or importing into the United States, without authorization, the Accused Products that practice various claims of the '624 Patent literally or under the doctrine of equivalents.

ANSWER: Denied.

109. Willow has complied with all statutory requirements, including the requirements of 35 U.S.C. § 287, to pursue and recover for any infringement of the '624 Patent.

ANSWER: Elvie lacks sufficient knowledge and information to form a belief as to the truth of the allegations of Paragraph 109 as pled and denies those allegations on that basis. Elvie further denies that Willow's virtual patent marking provides sufficient notice to the public of each patent covering each of Willow's products.

110. As a non-limiting example, the Accused Products meet every element of at least Claim 1 of the '624 Patent literally or under the doctrine of equivalents. Claim 1 recites:

[preamble] An automated system for controlling pumping cycles to pump milk from a human breast, the system comprising:

[1a] a breast pump shaped to fit within a bra, the breast pump including:

[1b] a housing sized to fit within the bra;

[1c] a breast adapter configured to contact and form a seal with the breast, the breast adapter being attached to the housing and including a nipple receiving cavity;

[1d] a pumping mechanism contained within the housing, the pumping mechanism including a pumping, region above the nipple receiving cavity;

[1e] a wireless transmitter;

[1f] a milk collection container configured to contact the bra;

[1g] a sensor which detects when the milk collection container is full;

[1h] an indicator light: and

[1i] a controller contained within the housing that automatically changes application of suction on the human breast through the nipple receiving cavity by the pumping mechanism from a letdown phase to an expression mode, wherein the controller automatically changes application of the suction from the letdown phase to the expression mode upon sensing a letdown.

ANSWER: Denied.

111. Exhibit 14 to this Complaint is a claim chart showing a non-limiting example of how Elvie's breast pumps and applications satisfy Claim 1 literally or under the doctrine of equivalents. The components and functionality in this chart are representative of the components and functionality present in all Accused Products. Elvie thus directly infringed and continues to directly infringe each limitation of at least Claim 1 of the '624 Patent by making, using, selling, offering for sale in the United States, and/or importing into the United States, without authorization, the Accused Products.

ANSWER: Denied.

112. On information and belief, Elvie has known about the '624 Patent since at least its issuance on July 28, 2020. Elvie's knowledge is due to at least (1) its presence in the breast pump market and status as Willow's competitor; (2) its monitoring of competitors' patent applications and issued patents; (3) its claim that its Elvie Pump is substantially equivalent to the Willow Pump during FDA pre-market proceedings; and (4) Willow's substantial and continuous practice of providing constructive notice of its patents on its website. On information and belief, competitors such as Elvie generally monitor the patent applications, issued patents, and litigation activity of one another.

ANSWER: Denied.

113. For example, the '624 Patent was cited during the prosecution of one or more of Elvie's patent applications. *See* Ex. 10 (U.S. Patent No. 11,413,380, assigned to Elvie, citing U.S. Pat. App. Pub. No. 2016/0310650—the parent application of the '624 Patent). Accordingly, Elvie had pre-suit knowledge of the '624 Patent at least through its prosecution activities.

ANSWER: Elvie admits that U.S. Patent Publication No. 2016/0310650 appears on the face of U.S. Patent No. 11,413,380 under "References Cited." Elvie specifically denies that the citation of U.S. Patent Publication No. 2016/0310650 is equivalent to knowledge of the issued '624 patent. Elvie denies the remaining allegations of Paragraph 113.

114. In the alternative, at least as of the filing date of this lawsuit, Elvie has had knowledge of the '624 Patent and knowledge of how Elvie and third parties infringe that patent.

ANSWER: Denied.

115. Elvie's knowledge of the '624 Patent is sufficient to satisfy the knowledge element for induced, contributory, and willful infringement.

ANSWER: Denied.

116. Elvie indirectly infringes at least Claim 1 of the '624 Patent in violation of 35 U.S.C. § 271(b) by taking active steps to encourage and facilitate direct infringement by third parties, including users, partners, affiliates, subsidiaries, and service providers, in the United States with knowledge and the specific intent that its efforts would result in the direct infringement of the '624 Patent. For example, Elvie actively induces infringement of the '624 Patent by designing, manufacturing, selling, or distributing the Accused Products and then training its customers and users on the use of those products and the accompanying mobile applications, including through the creation and dissemination of supporting materials, videos, instructions, product manuals, and technical information. See, e.g., <https://www.elvie.com/en-us/support/elvie-pump/using-elvie-pump-app/can-i-use-elvie-pump-without-the-app>. In addition, Elvie actively induces infringement of the '624 Patent by instructing, encouraging, or requiring its subsidiaries and affiliates to make, use, sell, offer for sale in the United States, and import into the United States, without authorization, the Accused Products that practice various claims of the '624 Patent, such as the Elvie Pump that is used in combination with the corresponding mobile applications. Further, Elvie actively induces infringement of the '624 Patent through the creation and dissemination of promotional and marketing materials. <https://www.youtube.com/watch?v=EXumEnA5qAw&t=95s>. Elvie's active inducement is done with the knowledge and the specific intent that its efforts would result in the direct infringement of the '624 Patent.

ANSWER: Denied.

117. Elvie also is liable for contributory infringement of the '624 Patent under 35 U.S.C. § 271(c) by selling or offering for sale the Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) in the United States and importing the Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) into the United States with knowledge that they are especially designed or adapted to operate in a manner that infringes the '624 Patent and are not a staple article or commodity of commerce suitable for substantial non-infringing use. Elvie contributes to infringement of the '624 Patent by, inter alia, promotion, and/or sales of the infringing Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) to third parties.

ANSWER: Denied.

118. Elvie's infringement of the '624 Patent has been and continues to be willful. As described above, Elvie has had knowledge of the '624 Patent at least since its issuance on July 28, 2020. On its website, Willow has provided substantial and continuous notice to infringers such as Elvie regarding the Asserted Patents, and Willow has included in such notice an identification of Willow products that practice the Asserted Patents. Thus, as one of Willow's primary competitors, Elvie had actual knowledge of the '624 Patent or was willfully blind to its existence. In the alternative, Elvie's infringement has been willful at least since the filing date of this lawsuit because it has deliberately continued to infringe the '624 Patent despite knowing of the patent and how Elvie infringes. Further, Willow has deliberately continued to encourage others' infringement of the '624 Patent, including by continuing to disseminate its marketing and technical materials to customers.

ANSWER: Denied.

119. Elvie's acts of infringement have injured and damaged Willow and will continue to injure and damage Willow. Willow is therefore entitled to recover from Elvie the damages it has sustained as a result of Elvie's wrongful and continued acts in an amount to be proven at trial.

ANSWER: Denied.

120. Elvie's infringement has damaged and will continue to damage Willow irreparably, and Willow has no adequate remedy at law for its injuries. In addition to actual damages, Willow is entitled to a permanent injunction enjoining Elvie from infringing the '624 Patent.

ANSWER: Denied.

COUNT V: INFRINGEMENT OF U.S. PATENT NO. 11,185,619

121. Willow incorporates by reference the proceeding paragraphs as if fully set forth herein.

ANSWER: Elvie incorporates by reference its responses to paragraphs 1 through 120.

122. Elvie has directly infringed, and continues to directly infringe, the '619 Patent in violation of 35 U.S.C. § 271(a) by making, using, selling, offering for sale in the United States, and/or importing into the United States, without authorization, the Accused Products that practice various claims of the '619 Patent literally or under the doctrine of equivalents.

ANSWER: Denied.

123. Willow has complied with all statutory requirements, including the requirements of 35 U.S.C. § 287, to pursue and recover for any infringement of the '619 Patent.

ANSWER: Elvie lacks sufficient knowledge and information to form a belief as to the truth of the allegations of Paragraph 123 as pled and denies those allegations on that basis. Elvie further denies that Willow's virtual patent marking provides sufficient notice to the public of each patent covering each of Willow's products.

124. As a non-limiting example, the Accused Products meet every element of at least Claim 1 of the '619 Patent literally or under the doctrine of equivalents. Claim 1 recites:

[preamble] An automated system for controlling pumping cycles to pump milk from a human breast, the automated system comprising:

[1a] a breast pump shaped to fit within a bra, the breast pump including:

[1b] a housing;

[1c] a vacuum pumping mechanism contained within the housing and configured to pump the milk from the human breast;

[1d] a wireless transmitter;

[1e] a skin contact member configured to contact and form a seal with the breast, the skin contact member attached to the housing and including a nipple receiving portion;

[1f] a milk collection container having a rigid exterior surface configured to contact the bra; and

[1g] a non-contact pressure sensor that measures vacuum levels within the automated system, the non-contact pressure sensor adjacent the nipple receiving portion.

ANSWER: Denied.

125. Exhibit 15 to this Complaint is a claim chart showing a non-limiting example of how Elvie's breast pumps and applications satisfy Claim 1 literally or under the doctrine of equivalents. The components and functionality in this chart are representative of the components and functionality present in all Accused Products. Elvie thus directly infringed and continues to directly infringe each limitation of at least Claim 1 of the '619 Patent by making, using, selling, offering for sale in the United States, and/or importing into the United States, without authorization, the Accused Products.

ANSWER: Denied.

126. On information and belief, Elvie has known about the '619 Patent since at least its

issuance on November 30, 2021. Elvie's knowledge is due to at least (1) its presence in the breast pump market and status as Willow's competitor; (2) its monitoring of competitors' patent applications and issued patents; (3) its claim that its Elvie Pump is substantially equivalent to the Willow Pump during FDA pre-market proceedings; and (4) Willow's substantial and continuous practice of providing constructive notice of its patents on its website. On information and belief, competitors such as Elvie generally monitor the patent applications, issued patents, and litigation activity of one another.

ANSWER: Denied.

127. For example, the '619 Patent was cited during the prosecution of one or more of Elvie's patent applications. *See* Ex. 10 (U.S. Patent No. 11,413,380, assigned to Elvie, citing U.S. Pat. App. Pub. No. 2018/0021490—the parent application to the '619 Patent). Accordingly, Elvie had pre-suit knowledge of the '619 Patent at least through its prosecution activities.

ANSWER: Elvie admits that U.S. Patent Publication No. 2018/0021490 appears on the face of U.S. Patent No. 11,413,380 under "References Cited." Elvie specifically denies that the citation of U.S. Patent Publication No. 2018/0021490 is equivalent to knowledge of the issued '619 patent. Elvie denies the remaining allegations of Paragraph 127.

128. In the alternative, at least as of the filing date of this lawsuit, Elvie has had knowledge of the '619 Patent and knowledge of how Elvie and third parties infringe that patent.

ANSWER: Denied.

129. Elvie's knowledge of the '619 Patent is sufficient to satisfy the knowledge element for induced, contributory, and willful infringement.

ANSWER: Denied.

130. Elvie indirectly infringes at least Claim 1 of the '619 Patent in violation of 35 U.S.C. § 271(b) by taking active steps to encourage and facilitate direct infringement by third parties, including users, partners, affiliates, subsidiaries, and service providers, in the United States with knowledge and the specific intent that its efforts would result in the direct infringement of the '619 Patent. For example, Elvie actively induces infringement of the '619 Patent by designing, manufacturing, selling, or distributing the Accused Products and then training its customers and users on the use of those products and the accompanying mobile applications, including through the creation and dissemination of supporting materials, videos, instructions, product manuals, and technical information. <https://www.elvie.com/en-us/support/elvie-pump/using-elvie-pump-app/can-i-use-elvie-pump-without-the-app>. In addition, Elvie

actively induces infringement of the '619 Patent by instructing, encouraging, or requiring its subsidiaries and affiliates to make, use, sell, offer for sale in the United States, and import into the United States, without authorization, the Accused Products that practice various claims of the '619 Patent, such as the Elvie Pump that is used in combination with the corresponding mobile applications. Further, Elvie actively induces infringement of the '619 Patent through the creation and dissemination of promotional and marketing materials.

<https://www.youtube.com/watch?v=EXumEnA5qAw&t=95s>. Elvie's active inducement is done with the knowledge and the specific intent that its efforts would result in the direct infringement of the '619 Patent.

ANSWER: Denied.

131. Elvie also is liable for contributory infringement of the '619 Patent under 35 U.S.C § 271(c) by selling or offering for sale the Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) in the United States and importing the Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) into the United States with knowledge that they are especially designed or adapted to operate in a manner that infringes the '619 Patent and are not a staple article or commodity of commerce suitable for substantial non-infringing use. Elvie contributes to infringement of the '619 Patent by, inter alia, promotion, and/or sales of the infringing Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) to third parties.

ANSWER: Denied.

132. Elvie's infringement of the '619 Patent has been and continues to be willful. As described above, Elvie has had knowledge of the '619 Patent at least since its issuance on November 30, 2021. On its website, Willow has provided substantial and continuous notice to infringers such as Elvie regarding the Asserted Patents, and Willow has included in such notice an identification of Willow products that practice the Asserted Patents. Thus, as one of Willow's primary competitors, Elvie had actual knowledge of the '619 Patent or was willfully blind to its existence. In the alternative, Elvie's infringement has been willful at least since the filing date of this lawsuit because it has deliberately continued to infringe the '619 Patent despite knowing of the patent and how Elvie infringes. Further, Willow has deliberately continued to encourage others' infringement of the '619 Patent, including by continuing to disseminate its marketing and technical materials to customers.

ANSWER: Denied.

133. Elvie's acts of infringement have injured and damaged Willow and will continue to injure and damage Willow. Willow is therefore entitled to recover from Elvie the damages it has sustained as a result of Elvie's wrongful and continued acts in an amount to be proven at trial.

ANSWER: Denied.

134. Elvie's infringement has damaged and will continue to damage Willow irreparably, and Willow has no adequate remedy at law for its injuries. In addition to actual damages, Willow is entitled to a permanent injunction enjoining Elvie from infringing the '619 Patent.

ANSWER: Denied.

COUNT VI: INFRINGEMENT OF U.S. DESIGN PATENT NO. D832,995

135. Willow incorporates by reference the proceeding paragraphs as if fully set forth herein.

ANSWER: Elvie incorporates by reference its responses to paragraphs 1 through 134.

136. Elvie has directly infringed, and continues to directly infringe, the 'D995 Patent in violation of 35 U.S.C. § 271(a) by making, using, selling, offering for sale in the United States, and/or importing into the United States, without authorization, the Accused Products that practice various claims of the 'D995 Patent literally or under the doctrine of equivalents.

ANSWER: Denied.

137. Willow has complied with all statutory requirements, including the requirements of 35 U.S.C. § 287 and § 289 to pursue and recover for any infringement of the 'D995 Patent.

ANSWER: Elvie lacks sufficient knowledge and information to form a belief as to the truth of the allegations of Paragraph 137 as pled and denies those allegations on that basis. Elvie further denies that Willow's virtual patent marking provides sufficient notice to the public of each patent covering each of Willow's products.

138. The 'D995 Patent claims the design as shown in the drawings contained therein. Each of the Accused Products is the same, or is substantially identical to, the design claimed in the 'D995 Patent as shown in the drawings contained therein. The following comparison of drawings contained in the 'D995 Patent to the Accused Products shows that each of the Accused Products is the same, or is substantially identical to, the design claimed in the 'D995 Patent.

U.S. Patent No. D832,995	Elvie Pump
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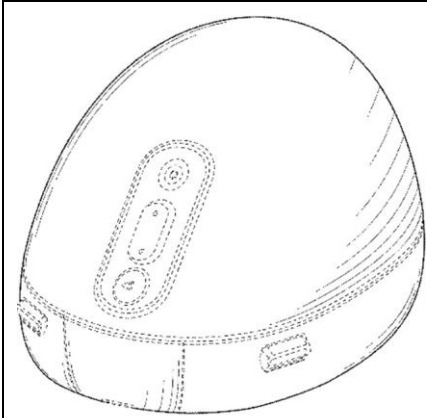


FIG. 1

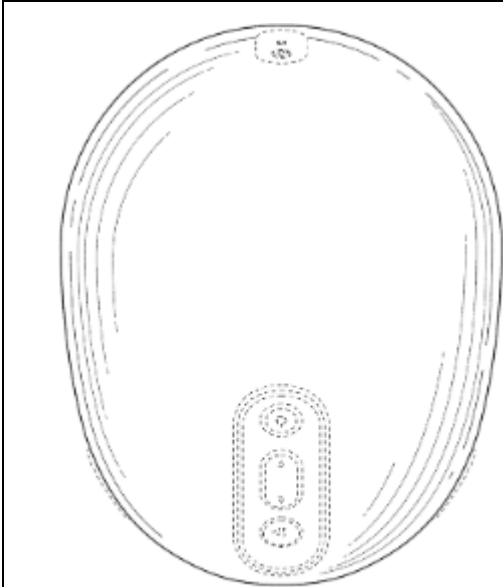


FIG. 6





ANSWER: Denied.

139. Comparing the drawings in the 'D995 patent with the Accused Products as shown above, an ordinary observer, with an understanding of the relevant prior art in breast pumps, would be deceived into believing that each of the Accused Products is the same as the patented design of the 'D995 patent. Each of the Accused Products is identical to, or substantially the same as, the patented design of the 'D995 Patent.

ANSWER: Denied.

140. On information and belief, Elvie has known about the 'D995 Patent since at least its issuance on November 6, 2018. Elvie's knowledge is due to at least (1) its presence in the breast pump market and status as Willow's competitor; (2) its monitoring of competitors' patent applications and issued patents; (3) its claim that its Elvie Pump is substantially equivalent to the Willow Pump during FDA pre-market proceedings; and (4) Willow's substantial and continuous practice of providing constructive notice of its patents on its website. On information and belief, competitors such as Elvie generally monitor the patent applications, issued patents, and litigation activity of one another.

ANSWER: Denied.

141. For example, the 'D995 Patent was cited during the prosecution of Elvie's patent applications. *See* Exs. 10, 11 (U.S. Patent Nos. 11,413,380 and D954,933, assigned to Elvie, citing the 'D995 Patent). Accordingly, Elvie had pre-suit knowledge of the 'D995 Patent at least through its prosecution activities.

ANSWER: Elvie admits that the 'D995 patent appears on the face of U.S. Patent Nos.

11,413,380 and D954,933 under "References Cited." Elvie denies the remaining allegations of

Paragraph 141.

142. In the alternative, at least as of the filing date of this lawsuit, Elvie has had knowledge of the '995 Patent and knowledge of how Elvie and third parties infringe that patent.

ANSWER: Denied.

143. Elvie's knowledge of the 'D995 Patent is sufficient to satisfy the knowledge element for induced, contributory, and willful infringement.

ANSWER: Denied.

144. Elvie indirectly infringes at least Claim 1 of the 'D995 Patent in violation of 35 U.S.C. § 271(b) by taking active steps to encourage and facilitate direct infringement by third parties, including users, partners, affiliates, subsidiaries, and service providers, in the United States with knowledge and the specific intent that its efforts would result in the direct infringement of the 'D995 Patent. For example, Elvie actively induces infringement of the 'D995 Patent by designing, manufacturing, selling, or distributing the Accused Products and then training its customers and users on the use of those products and the accompanying mobile applications, including through the creation and dissemination of supporting materials, videos, instructions, product manuals, and technical information. <https://www.elvie.com/en-us/support/elvie-pump/using-elvie-pump-app/can-i-use-elvie-pump-without-the-app>. In addition, Elvie actively induces infringement of the 'D995 Patent by instructing, encouraging, or requiring its subsidiaries and affiliates to make, use, sell, offer for sale in the United States, and import into the United States, without authorization, the Accused Products that practice various claims of the 'D995 Patent, such as the Elvie Pump that is used in combination with the corresponding mobile applications. Further, Elvie actively induces infringement of the 'D995 Patent through the creation and dissemination of promotional and marketing materials. <https://www.youtube.com/watch?v=EXumEnA5qAw&t=95s>. Elvie's active inducement is done with the knowledge and the specific intent that its efforts would result in the direct infringement of the 'D995 Patent.

ANSWER: Denied.

145. Elvie also is liable for contributory infringement of the 'D995 Patent under 35 U.S.C. § 271(c) by selling or offering for sale the Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) in the United States and importing the Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) into the United States with knowledge that they are especially designed or adapted to operate in a manner that infringes the 'D995 Patent and are not a staple article or commodity of commerce suitable for substantial non-infringing use. Elvie contributes to infringement of the 'D995 Patent by, inter alia, promotion, and/or sales of the infringing Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) to third parties.

ANSWER: Denied.

146. Elvie's infringement of the 'D995 Patent has been and continues to be willful. As described above, Elvie has had knowledge of the 'D995 Patent at least since its issuance on November 6, 2018. On its website, Willow has provided substantial and continuous notice to infringers such as Elvie regarding the Asserted Patents, and Willow has included in such notice an identification of Willow products that practice the Asserted Patents. Thus, as one of Willow's primary competitors, Elvie had actual knowledge of the 'D995 Patent or was willfully blind to its existence. In the alternative, Elvie's infringement has been willful at least since the filing date of this lawsuit because it has deliberately continued to infringe the 'D995 Patent despite knowing of the patent and how Elvie infringes. Further, Willow has deliberately continued to encourage others' infringement of the 'D995 Patent, including by continuing to disseminate its marketing and technical materials to customers.

ANSWER: Denied.

147. Elvie's acts of infringement have injured and damaged Willow and will continue to injure and damage Willow. Willow is therefore entitled to recover from Elvie the damages it has sustained as a result of Elvie's wrongful and continued acts in an amount to be proven at trial.

ANSWER: Denied.

148. Elvie's infringement has damaged and will continue to damage Willow irreparably, and Willow has no adequate remedy at law for its injuries. In addition to actual damages, Willow is entitled to a permanent injunction enjoining Elvie from infringing the 'D995 Patent.

ANSWER: Denied.

COUNT VII: INFRINGEMENT OF U.S. DESIGN PATENT NO. D977,625

149. Willow incorporates by reference the proceeding paragraphs as if fully set forth herein.

ANSWER: Elvie incorporates by reference its responses to paragraphs 1 through 148.

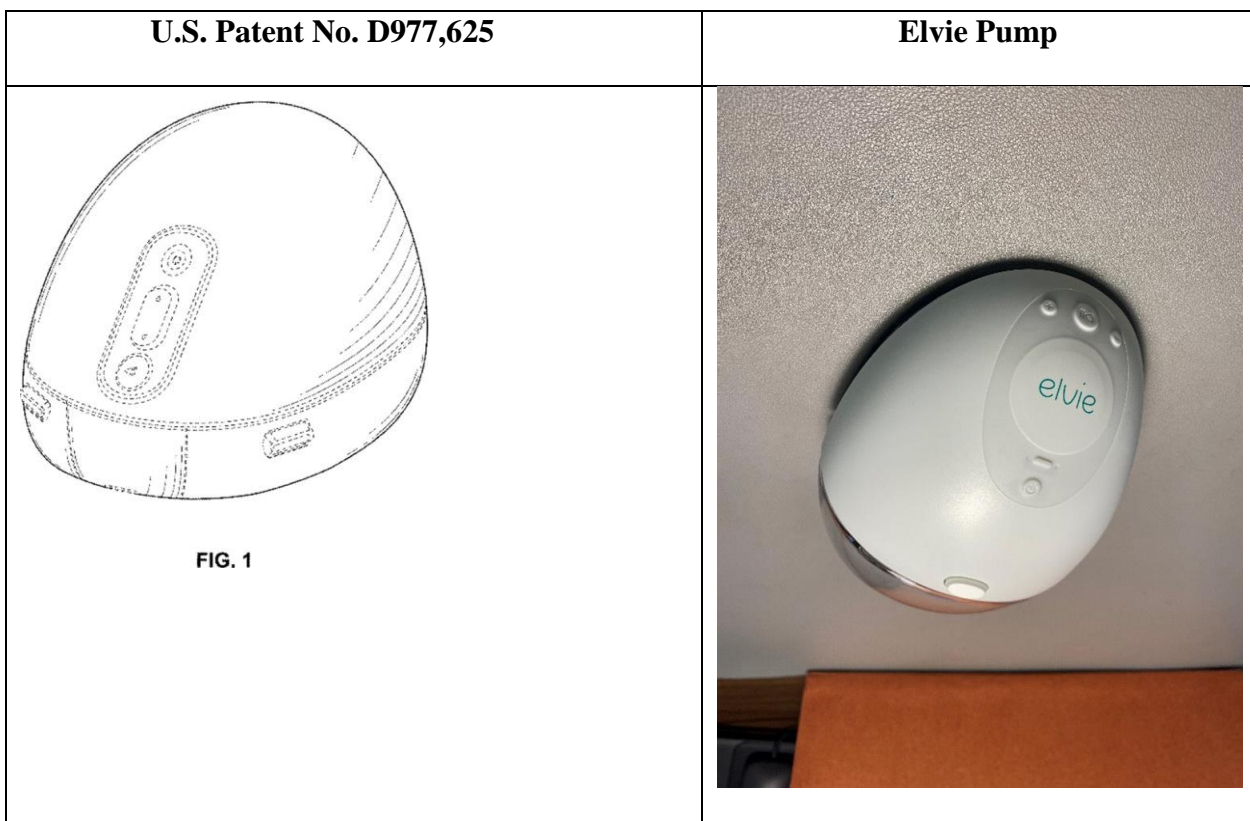
150. Elvie has directly infringed, and continues to directly infringe, the 'D625 Patent in violation of 35 U.S.C. § 271(a) by making, using, selling, offering for sale in the United States, and/or importing into the United States, without authorization, the Accused Products that practice various claims of the 'D625 Patent literally or under the doctrine of equivalents.

ANSWER: Denied.

151. Willow has complied with all statutory requirements, including the requirements of 35 U.S.C. § 287 and § 289, to pursue and recover for any infringement of the 'D625 Patent.

ANSWER: Elvie lacks sufficient knowledge and information to form a belief as to the truth of the allegations of Paragraph 151 as pled and denies those allegations on that basis. Elvie further denies that Willow's virtual patent marking provides sufficient notice to the public of each patent covering each of Willow's products.

152. The 'D625 Patent claims the design as shown in the drawings contained therein. Each of the Accused Products is the same, or is substantially identical to, the design claimed in the 'D625 Patent as shown in the drawings contained therein. The following comparison of drawings contained in the 'D625 Patent to the Accused Products shows that each of the Accused Products is the same, or is substantially identical to, the design claimed in the 'D625 Patent.





ANSWER: Denied.

153. Comparing the drawings in the 'D625 patent with the Accused Products as shown above, an ordinary observer, with an understanding of the relevant prior art in breast pumps, would be deceived into believing that each of the Accused Products is the same as the patented design of the 'D995 patent. Each of the Accused Products is identical to, or substantially the same as, the patented design of the 'D625 Patent.

ANSWER: Denied.

154. On information and belief, Elvie has known about the 'D625 Patent since at least its issuance on February 7, 2023. Elvie's knowledge is due to at least (1) its presence in the breast pump market and status as Willow's competitor; (2) its monitoring of competitors' patent applications and issued patents; (3) its claim that its Elvie Pump is substantially equivalent to the Willow Pump during FDA pre-market proceedings; and (4) Willow's substantial and continuous practice of providing constructive notice of its patents on its website. On information and belief, competitors such as Elvie generally monitor the patent applications, issued patents, and litigation activity of one another.

ANSWER: Denied.

155. For example, the 'D625 Patent was cited during the prosecution of Elvie's patent applications. See Exs. 10, 11 (U.S. Patent Nos. 11,413,380 and D954,933, assigned to Elvie, citing U.S. Design Patent No. D832,995—the parent patent to the 'D625 Patent). Accordingly, Elvie had pre-suit knowledge of the '624 Patent at least through its prosecution activities.

ANSWER: Elvie admits that the 'D625 patent appears on the face of U.S. Patent Nos.

11,413,380 and D954,933 citing U.S. Design Patent No. D832,995 under "References Cited."

Elvie denies the remaining allegations of Paragraph 155.

156. In the alternative, at least as of the filing date of this lawsuit, Elvie has had knowledge of the 'D625 Patent and knowledge of how Elvie and third parties infringe that patent.

ANSWER: Denied.

157. Elvie's knowledge of the 'D625 Patent is sufficient to satisfy the knowledge element for induced, contributory, and willful infringement.

ANSWER: Denied.

158. Elvie indirectly infringes at least Claim 1 of the 'D625 Patent in violation of 35 U.S.C. § 271(b) by taking active steps to encourage and facilitate direct infringement by third parties, including users, partners, affiliates, subsidiaries, and service providers, in the United States with knowledge and the specific intent that its efforts would result in the direct infringement of the '625 Patent. For example, Elvie actively induces infringement of the 'D625 Patent by designing, manufacturing, selling, or distributing the Accused Products and then training its customers and users on the use of those products and the accompanying mobile applications, including through the creation and dissemination of supporting materials, videos, instructions, product manuals, and technical information. <https://www.elvie.com/en-us/support/elvie-pump/using-elvie-pump-app/can-i-use-elvie-pump-without-the-app>. In addition, Elvie actively induces infringement of the 'D625 Patent by instructing, encouraging, or

requiring its subsidiaries and affiliates to make, use, sell, offer for sale in the United States, and import into the United States, without authorization, the Accused Products that practice various claims of the 'D625 Patent, such as the Elvie Pump that is used in combination with the corresponding mobile applications. Further, Elvie actively induces infringement of the 'D625 Patent through the creation and dissemination of promotional and marketing materials.

<https://www.youtube.com/watch?v=EXumEnA5qAw&t=95s>. Elvie's active inducement is done with the knowledge and the specific intent that its efforts would result in the direct infringement of the 'D625 Patent.

ANSWER: Denied.

159. Elvie also is liable for contributory infringement of the 'D625 Patent under 35 U.S.C § 271(c) by selling or offering for sale the Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) in the United States and importing the Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) into the United States with knowledge that they are especially designed or adapted to operate in a manner that infringes the 'D625 Patent and are not a staple article or commodity of commerce suitable for substantial non-infringing use. Elvie contributes to infringement of the 'D625 Patent by, inter alia, promotion, and/or sales of the infringing Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) to third parties.

ANSWER: Denied.

160. Elvie's infringement of the 'D625 Patent has been and continues to be willful. As described above, Elvie has had knowledge of the 'D625 Patent at least since its issuance on April 21, 2020. On its website, Willow has provided substantial and continuous notice to infringers such as Elvie regarding the Asserted Patents, and Willow has included in such notice an identification of Willow products that practice the Asserted Patents. Thus, as one of Willow's primary competitors, Elvie had actual knowledge of the 'D625 Patent or was willfully blind to its existence. In the alternative, Elvie's infringement has been willful at least since the filing date of this lawsuit because it has deliberately continued to infringe the 'D625 Patent despite knowing of the patent and how Elvie infringes. Further, Willow has deliberately continued to encourage others' infringement of the 'D625 Patent, including by continuing to disseminate its marketing and technical materials to customers.

ANSWER: Denied.

161. Elvie's acts of infringement have injured and damaged Willow and will continue to injure and damage Willow. Willow is therefore entitled to recover from Elvie the damages it has sustained as a result of Elvie's wrongful and continued acts in an amount to be proven at trial.

ANSWER: Denied.

162. Elvie's infringement has damaged and will continue to damage Willow irreparably, and Willow has no adequate remedy at law for its injuries. In addition to actual damages, Willow is entitled to a permanent injunction enjoining Elvie from infringing the 'D625 Patent.

ANSWER: Denied.

COUNT VII: INFRINGEMENT OF U.S. PATENT NO. 10,688,229

163. Willow incorporates by reference the proceeding paragraphs as if fully set forth herein.

ANSWER: Elvie incorporates by reference its responses to paragraphs 1 through 162.

164. Elvie has directly infringed, and continues to directly infringe, the '229 Patent in violation of 35 U.S.C. § 271(a) by making, using, selling, offering for sale in the United States, and/or importing into the United States, without authorization, the Accused Products that practice various claims of the '229 Patent literally or under the doctrine of equivalents.

ANSWER: Denied.

165. Willow has complied with all statutory requirements, including the requirements of 35 U.S.C. § 287, to pursue and recover for any infringement of the '229 Patent.

ANSWER: Elvie lacks sufficient knowledge and information to form a belief as to the truth of the allegations of Paragraph 165 as pled and denies those allegations on that basis. Elvie further denies that Willow's virtual patent marking provides sufficient notice to the public of each patent covering each of Willow's products.

166. As a non-limiting example, the Accused Products meet every element of at least Claim 1 of the '229 Patent literally or under the doctrine of equivalents. Claim 1 recites:

[preamble] A wearable, portable self-powered breast pump system for pumping milk from a breast, comprising:

[1a] a main body;

[1b] a breast adapter;

[1c] a milk collection container; and

[1d] a pump mechanism configured to pump milk from the breast to the milk

collection container;

[1e] wherein the breast adapter, the pump mechanism and the milk collection container are collectively sized and shaped to fit within a user's bra, and the pump mechanism and milk collection container are contained within the main body;

[1f] wherein a latch suction is maintained throughout a pumping session.

ANSWER: Denied.

167. Exhibit 17 to this Complaint is a claim chart showing a non-limiting example of how Elvie's breast pumps and applications satisfy Claim 1 literally or under the doctrine of equivalents. The components and functionality in this chart are representative of the components and functionality present in all Accused Products. Elvie thus directly infringed and continues to directly infringe each limitation of at least Claim 1 of the '229 Patent by making, using, selling, offering for sale in the United States, and/or importing into the United States, without authorization, the Accused Products.

ANSWER: Denied.

168. On information and belief, Elvie has known about the '229 Patent since at least its issuance on June 23, 2020. Elvie's knowledge is due to at least (1) its presence in the breast pump market and status as Willow's competitor; (2) its monitoring of competitors' patent applications and issued patents; (3) its claim that its Elvie Pump is substantially equivalent to the Willow Pump during FDA pre-market proceedings; and (4) Willow's substantial and continuous practice of providing constructive notice of its patents on its website. On information and belief, competitors such as Elvie generally monitor the patent applications, issued patents, and litigation activity of one another.

ANSWER: Denied.

169. For example, the '229 Patent was cited during the prosecution of Elvie's patent applications. *See* Ex. 10 (U.S. Patent No. 11,413,380, assigned to Elvie, citing U.S. Patent Publication No. 2016/0310650, the published application of the issued '229 Patent). Accordingly, Elvie had pre-suit knowledge of the '229 Patent at least through its prosecution activities.

ANSWER: Elvie admits that U.S. Patent Publication No. 2016/0310650 appears on the face of U.S. Patent No. 11,413,380 under "References Cited." Elvie specifically denies that the citation of U.S. Patent Publication No. 2016/0310650 is equivalent to knowledge of the issued patent. Elvie denies the remaining allegations of Paragraph 169.

170. In the alternative, at least as of the filing date of this lawsuit, Elvie has had knowledge of the '229 Patent and knowledge of how Elvie and third parties infringe that patent.

ANSWER: Denied.

171. Elvie's knowledge of the '229 Patent is sufficient to satisfy the knowledge element for induced, contributory, and willful infringement.

ANSWER: Denied.

172. Elvie indirectly infringes at least Claim 1 of the '229 Patent in violation of 35 U.S.C. § 271(b) by taking active steps to encourage and facilitate direct infringement by third parties, including users, partners, affiliates, subsidiaries, and service providers, in the United States with knowledge and the specific intent that its efforts would result in the direct infringement of the '229 Patent. For example, Elvie actively induces infringement of the '229 Patent by designing, manufacturing, selling, or distributing the Accused Products and then training its customers and users on the use of those products and the accompanying mobile applications, including through the creation and dissemination of supporting materials, videos, instructions, product manuals, and technical information. <https://www.elvie.com/en-us/support/elvie-pump/using-elvie-pump-app/can-i-use-elvie-pump-without-the-app>. In addition, Elvie actively induces infringement of the '229 Patent by instructing, encouraging, or requiring its subsidiaries and affiliates to make, use, sell, offer for sale in the United States, and import into the United States, without authorization, the Accused Products that practice various claims of the '229 Patent, such as the Elvie Pump that is used in combination with the corresponding mobile applications. Further, Elvie actively induces infringement of the '229 Patent through the creation and dissemination of promotional and marketing materials. <https://www.youtube.com/watch?v=EXumEnA5qAw&t=95s>. Elvie's active inducement is done with the knowledge and the specific intent that its efforts would result in the direct infringement of the '229 Patent.

ANSWER: Denied.

173. Elvie also is liable for contributory infringement of the '229 Patent under 35 U.S.C. § 271(c) by selling or offering for sale the Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) in the United States and importing the Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) into the United States with knowledge that they are especially designed or adapted to operate in a manner that infringes the '229 Patent and are not a staple article or commodity of commerce suitable for substantial non-infringing use. Elvie contributes to infringement of the '229 Patent by, *inter alia*, promotion, and/or sales of the infringing Accused Products and/or other components (e.g., breast pump accessories, mobile applications, etc.) to third parties.

ANSWER: Denied.

174. Elvie's infringement of the '229 Patent has been and continues to be willful. As described above, Elvie has had knowledge of the '229 Patent at least since its issuance on June 23, 2020. On its website, Willow has provided substantial and continuous notice to infringers such as Elvie regarding the Asserted Patents, and Willow has included in such notice an identification of Willow products that practice the Asserted Patents. Thus, as one of Willow's primary competitors, Elvie had actual knowledge of the '229 Patent or was willfully blind to its existence. In the alternative, Elvie's infringement has been willful at least since the filing date of this lawsuit because it has deliberately continued to infringe the '229 Patent despite knowing of the patent and how Elvie infringes. Further, Willow has deliberately continued to encourage others' infringement of the '229 Patent, including by continuing to disseminate its marketing and technical materials to customers.

ANSWER: Denied.

175. Elvie's acts of infringement have injured and damaged Willow and will continue to injure and damage Willow. Willow is therefore entitled to recover from Elvie the damages it has sustained as a result of Elvie's wrongful and continued acts in an amount to be proven at trial.

ANSWER: Denied.

176. Elvie's infringement has damaged and will continue to damage Willow irreparably, and Willow has no adequate remedy at law for its injuries. In addition to actual damages, Willow is entitled to a permanent injunction enjoining Elvie from infringing the '229 Patent

ANSWER: Denied.

**COUNT IX: FEDERAL FALSE ADVERTISING UNDER SECTION 43(A) OF THE
LANHAM ACT, 15 U.S.C. § 1125(A)(1)(B)**

177. Willow restates and incorporates by reference the preceding paragraphs as if fully set forth herein.

ANSWER: Elvie incorporates by reference its responses to paragraphs 1 through 176.

178. Elvie uses the description or representation that its Elvie Pump is "silent" in its commercial advertising and promotion.

ANSWER: Paragraph 178 contains legal conclusions and allegations to which no response is required. To the extent a response is required, Elvie admits that Plaintiff purports to present an incomplete selection or summary of text from Elvie's commercial advertising and

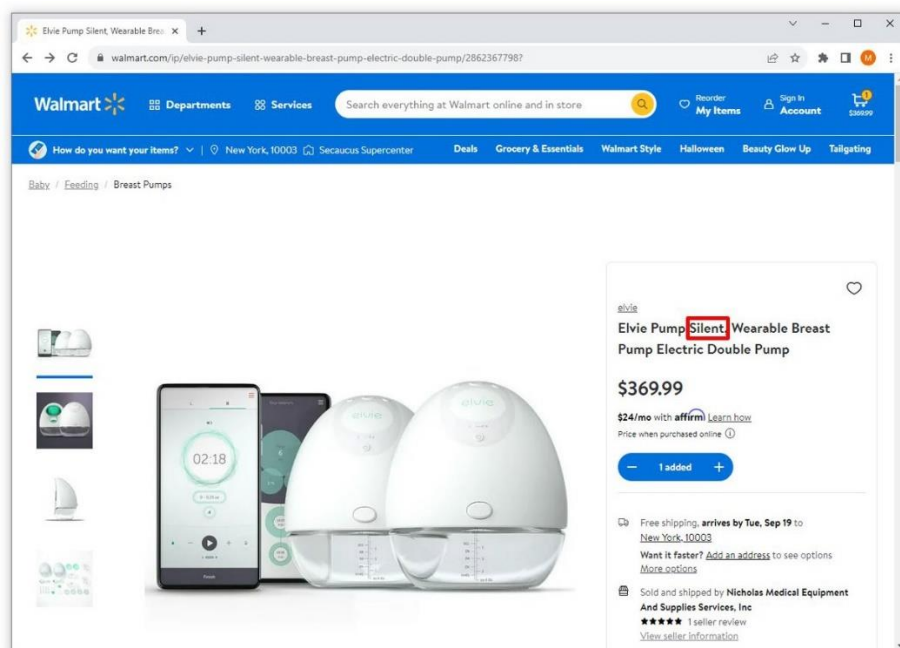
promotion, but the actual and complete disclosure of the advertisements and promotions speak for themselves and are controlling. Elvie denies the remaining allegations of Paragraph 178.

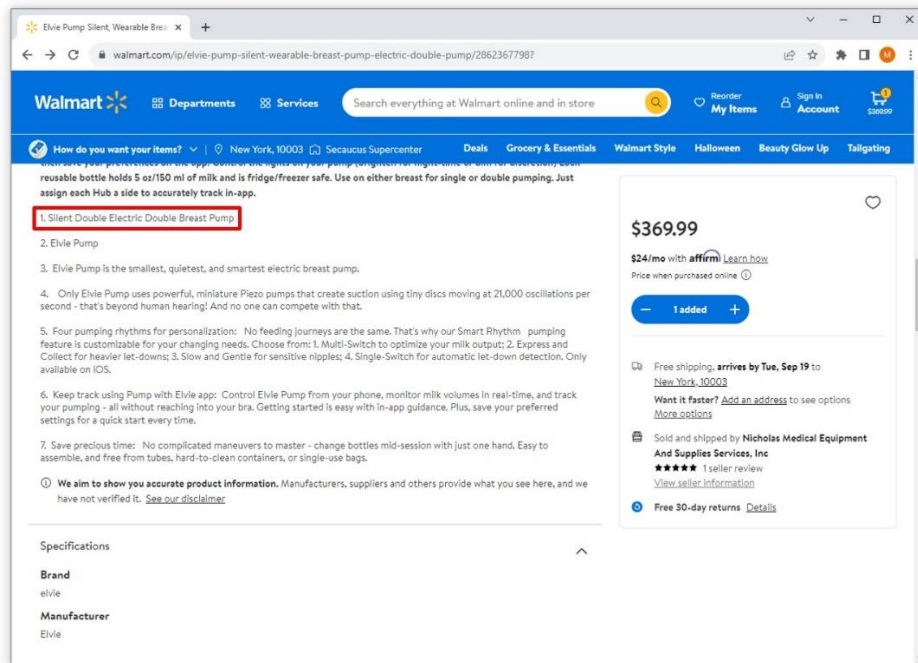
179. For example, Elvie describes the Elvie Pump as “[s]ilent” and that “[n]obody will hear a thing” on its packaging, as shown below (annotations added), and sells the Elvie Pump via its online store at <http://www.elvie.com> and through retailers and online marketplaces, such as Walmart and Amazon, to consumers in the United States.



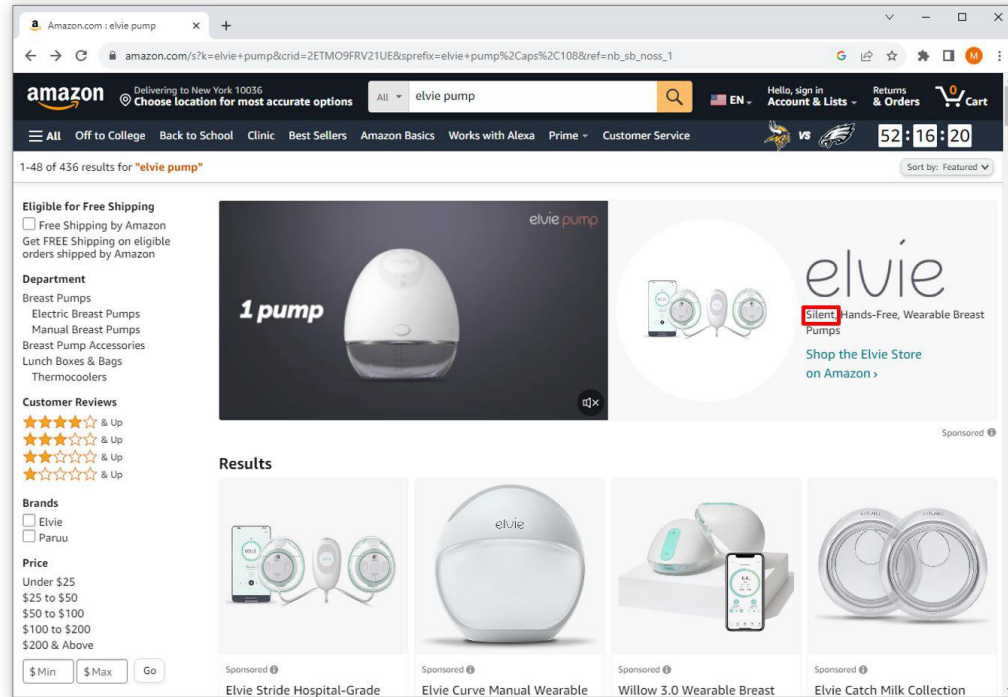
ANSWER: Elvie admits that it has made its products available for sale on its website, as well as other retailer websites including Walmart and Amazon. Elvie admits that Plaintiff purports to present an incomplete selection or summary of text from Elvie’s packaging, but the actual and complete disclosures of the packaging speak for themselves and are controlling. Elvie denies the remaining allegations of Paragraph 179.

180. Elvie describes or advertises the Elvie Pump as “silent” on online marketplaces including Walmart.com and Amzaon.com, as shown below (annotations added).



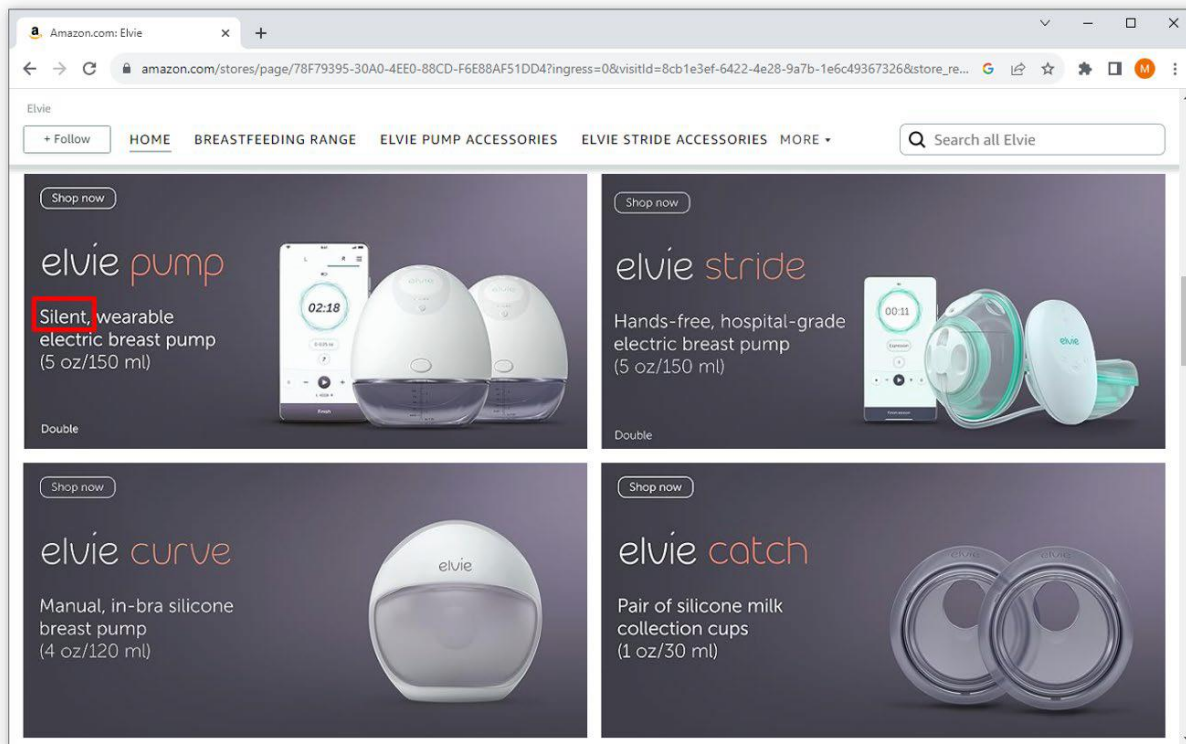


Elvie Pump Silent, Wearable Breast Pump Electric Double Pump, Walmart.com (last visited September 12, 2023), <https://www.walmart.com/ip/elvie-pump-silent-wearable-breast-pump-electric-double-pump/2862367798>? (annotations added).



Elvie Sponsored Advertisement, Amazon.com (last visited September 12, 2023), <https://www.amazon.com/s?k=elvie+pump&crd=2ETMO9FRV21UE&sprefix=elvie>

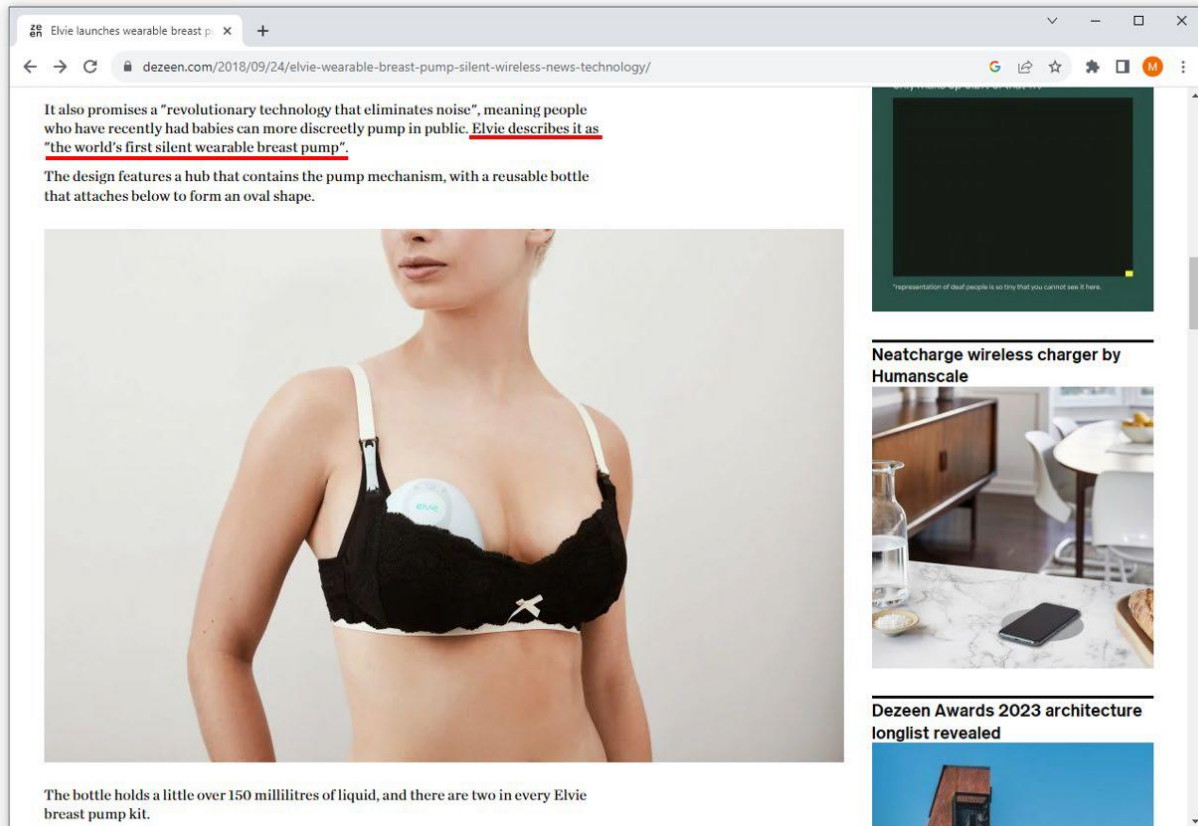
[+pump%2Caps%2C108&ref=nb_sb_noss_1](#) (annotations added).



Elvie Store on Amazon, Amazon.com (last visited April 26, 2024), https://www.amazon.com/stores/page/78F79395-30A0-4EE0-88CD-F6E88AF51DD4?ingress=0&visitId=8cb1e3ef-6422-4e28-9a7b-1e6c49367326&store_ref=SBV_A012182020M5NCDS4UWPI&ref_=sbx_be_s_spar_kle_ssd (annotation added).

ANSWER: Elvie admits that it has made its products available for sale on retailer websites including Walmart and Amazon. Elvie admits that Plaintiff purports to present an incomplete selection or summary of text from Elvie’s pages on retailer websites, but the actual and complete disclosures of the webpages speak for themselves and are controlling. Elvie denies the remaining allegations of Paragraph 180.

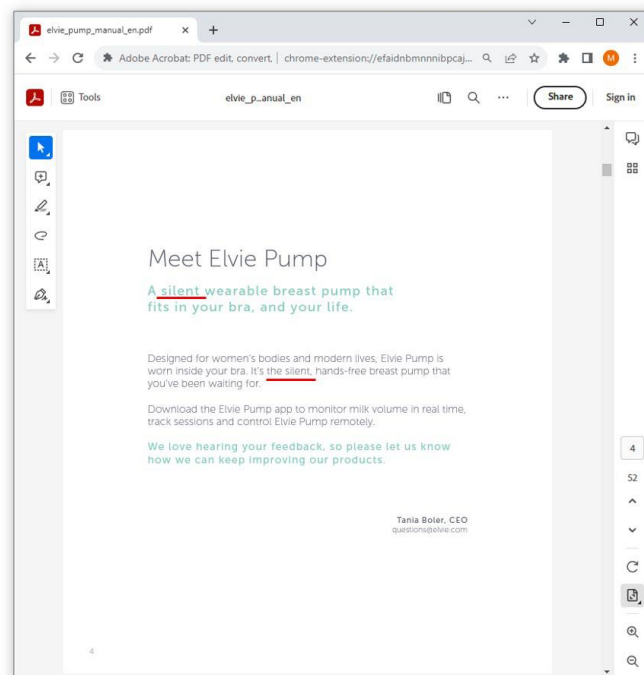
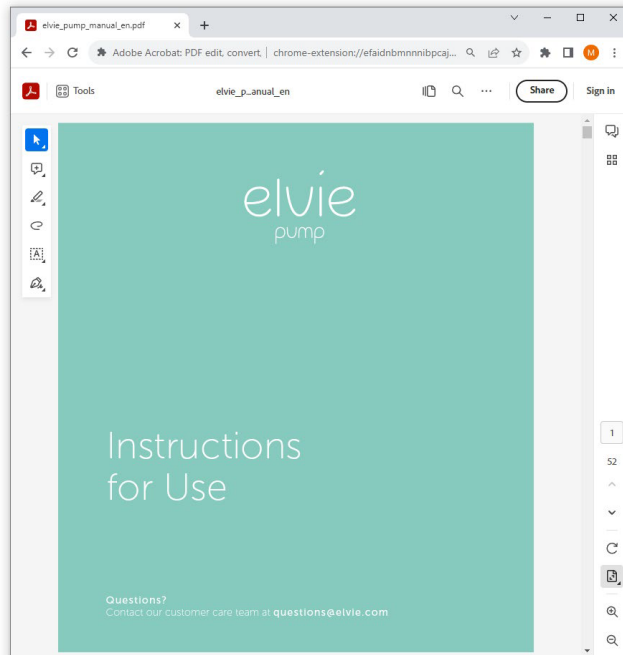
181. Elvie describes or promotes the Elvie Pump as “silent” to online publishers including Dezeen, as shown below (annotations added).



Elvie launches wearable breast pump that's silent and wireless, Dezeen (last visited April 26, 2024), <https://www.dezeen.com/2018/09/24/elvie-wearable-breast-pump-silent-wireless-news-technology/> ("Elvie describes [the Elvie Pump] as 'the world's first silent wearable breast pump.'").

ANSWER: Elvie admits that Plaintiff purports to present an incomplete selection or summary of text from a third party website discussing the Elvie Pump. Elvie denies the remaining allegations of Paragraph 181.

182. Elvie provides instruction manual of the Elvie Pump through its own online store at <http://www.elvie.com>. As shown below, the Elvie Pump instruction manual describes the Elvie Pump as a "silent" wearable breast pump (annotations added).



Elvie Pump – Instructions for User at 1, 4 (last visited April 26, 2024), https://www.elvie.com/assets/manuals/elvie_pump_manual_en.pdf (annotations added).

ANSWER: Elvie admits that Plaintiff purports to present an incomplete selection or summary of text from the instruction manual for the Elvie Pump, but the actual and complete

disclosures of the manual speak for themselves and are controlling. Elvie denies the remaining allegations of Paragraph 182.

183. Elvie's misrepresentations continue to this day. In its counterclaims, Elvie stated that the Elvie Pump "is the world's first silent, wearable breast pump." Dkt. 60, Second Amended Counterclaims, ¶ 13. Elvie repeated this misrepresentation in recent briefing submitted to this Court. See Dkt. 62, Elvie's Opposition to Willow's Motion to Dismiss, at 3 ("Elvie's second product, Elvie Pump, is the world's first silent, wearable breast pump.").

ANSWER: Paragraph 183 contains legal conclusions and allegations to which no response is required. To the extent a response is required, Elvie denies the allegations of Paragraph 183.

184. The Elvie Pump is not "silent" because it makes audible noises during operation.

ANSWER: Denied.

185. On information and belief, the Elvie Pump makes more than 31 decibels of noise during operation.

ANSWER: Elvie lacks sufficient knowledge and information to form a belief as to the truth of the allegations of Paragraph 185 as pled and denies those allegations on that basis.

186. Elvie's commercial descriptions or representations regarding the Elvie Pump being "silent" and that "nobody will hear a thing" are false or misleading.

ANSWER: Paragraph 186 contains legal conclusions and allegations to which no response is required. To the extent a response is required, Elvie denies the allegations of Paragraph 186.

187. Third party reviews have described being actually misled or deceived by Elvie's claims that the Elvie Pump is silent. Elvie breast pump review, The Sun (last visited April 26, 2024), <https://www.thesun.co.uk/shopping/product-reviews/24535383/elvie-breast-pump-review/> ("[The Elvie Pump is] not totally silent, so the brand's claim of 'no noise' is not fully justified."); Elvie Pump Review, Business Insider (last viewed April, 26, 2024), <https://www.businessinsider.com/guide/parenting/elvie-breast-pump-double-review> ("Though it's marketed as a 'silent' breast pump, the sound is noticeable.").

ANSWER: Elvie lacks sufficient knowledge and information to form a belief as to the

truth of the allegations of Paragraph 187 as pled and denies those allegations on that basis.

188. Elvie's actions described above in the commercial advertising or promotion misrepresent the nature, characteristics and quality of the Elvie Pump, and thus constitute false or misleading description of fact, or false or misleading representation of fact in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

ANSWER: Denied.

189. Elvie's falsely or misleadingly represented products are advertised, promoted, sold, and distributed in interstate commerce.

ANSWER: Denied.

190. Elvie has committed acts of false advertising by its dissemination of false or misleading advertising claims.

ANSWER: Denied.

191. Elvie's use of false or misleading representations of fact in commercial advertising or promotion misrepresents the nature, characteristics, or qualities of Elvie's products, including the Elvie Pump.

ANSWER: Denied.

192. Elvie's use of false or misleading representations of fact has the tendency to deceive a substantial portion of the target consumer audience (purchasers and potential purchasers of breast pumps and related products), or actually deceives the target consumers. For example, Elvie widely disseminates the false or misleading representations of fact in connection with its products, including the Elvie Pump, on its online store and on online marketplaces, such as Walmart and Amazon. On information and belief, the target consumer audience are deceived by these false or misleading representations of fact.

ANSWER: Denied.

193. Elvie's false or misleading representations of fact are material because they are likely to influence the purchasing decision of the target consumers. For example, Elvie's false or misleading representations of fact regarding the Elvie Pump being "silent" and that "[n]obody will hear a thing" are intended and likely to cause consumers to believe that Elvie and its products are superior to Willow and its products.

ANSWER: Denied.

194. Willow and Elvie are direct competitors in the wearable, under-the-bra breast

pump market.

ANSWER: Elvie lacks sufficient knowledge and information to form a belief as to the truth of the allegations of Paragraph 194 as pled and denies those allegations on that basis.

195. Willow has been and continues to be injured by Elvie's false or misleading representations of fact through the diversion of sales or loss of goodwill.

ANSWER: Denied.

196. On information and belief, Elvie knows that its representations of fact are false or misleading.

ANSWER: Denied.

197. On information and belief, Elvie's false or misleading representations of fact were done with bad faith and malice or reckless indifference to Willow's and consumers' interests.

ANSWER: Denied.

198. Elvie's bad faith false or misleading representations of fact regarding its products make this an exceptional case within the meaning of 15 U.S.C. § 1117.

ANSWER: Denied.

199. Elvie continues to make false or misleading representations of fact regarding the quality of its products and will continue to do so unless enjoined by this Court as provided by 15 U.S.C. § 1116.

ANSWER: Denied.

200. Willow is entitled to an award of Elvie's profits due to sales of the falsely or misleadingly represented products, any damages sustained by Willow, and the costs of the action, pursuant to 15 U.S.C. § 1117.

ANSWER: Denied.

COUNT X: UNFAIR COMPETITION UNDER TEXAS COMMON LAW

201. Willow restates and incorporates by reference the preceding paragraphs as if fully set forth herein.

ANSWER: Elvie incorporates by reference its responses to paragraphs 1 through 200.

202. Elvie has engaged in business conduct that is contrary to honest business practice

in industrial or commercial matters, including by its dissemination of false or misleading designations and advertising claims as alleged above.

ANSWER: Denied.

203. Elvie continues to make false or misleading representations of fact regarding the quality of its products and will continue to do so unless enjoined by this Court.

ANSWER: Denied.

204. Willow is entitled to an award of Elvie's profits due to sales of the falsely or misleadingly represented products, any damages sustained by Willow, and the costs of the action.

ANSWER: Denied.

JURY DEMAND

205. Willow hereby demands a trial by jury on all issues.

ANSWER: Defendant demands a jury on all issues so triable.

PRAYER FOR RELIEF

This section of Plaintiff's Complaint constitutes Prayers for Relief that do not require a response. Elvie denies that Plaintiff is entitled to any of the requested relief or any other relief whatsoever and, therefore, specifically deny Paragraphs (a) to (m) of the Complaint's Prayer for Relief. Each averment and/or allegation contained in Plaintiff's Complaint that is not specifically admitted herein is hereby denied.

DEFENSES

FIRST DEFENSE **(Failure to State a Claim)**

206. Plaintiff's Complaint fails to state a claim upon which relief may be granted.

SECOND DEFENSE **(Non-Infringement)**

207. Elvie has not and will not infringe, directly or indirectly, literally or under the

doctrine of equivalents, any valid and enforceable claim of the Asserted Patents and are not liable for any infringement thereof.

THIRD DEFENSE
(Invalidity)

208. Each claim of the Asserted Patents are invalid for failure to satisfy one or more conditions for patentability under the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or 171 and/or obviousness-type double patenting.

FOURTH DEFENSE
(Lack of Standing)

209. To the extent Plaintiff does not have substantially all the rights or all the rights to the Asserted Patents, or to the extent that the purported assignments of the Asserted Patents are defective for any reason, Plaintiff lacks standing to bring this action.

FIFTH DEFENSE
(Prosecution History Estoppel)

210. Plaintiff's claims are barred, in whole or in part, by prosecution history estoppel based on statements and/or amendments made by the applicants during prosecution of the Asserted Patents.

SIXTH DEFENSE
(Plaintiff's Patent Infringement Claims are Barred)

211. One or more of Plaintiff's patent infringement claims are barred by the equitable doctrines of acquiescence, waiver, estoppel, equitable estoppel, and/or unclean hands.

SEVENTH DEFENSE
(Plaintiff's Requested Relief is Barred)

212. One or more of the reliefs sought by Plaintiff are barred or limited pursuant to one or more sections of titles 35 and 15 of the U.S. Code and/or any other judicial or statutory requirement.

EIGHTH DEFENSE
(Limitations on Damages and Costs)

213. On information and belief, Plaintiff's right to seek damages and costs is limited, including and without limitation by 35 U.S.C. §§ 286, 287, and 288.

NINTH DEFENSE
(No Exceptional Case)

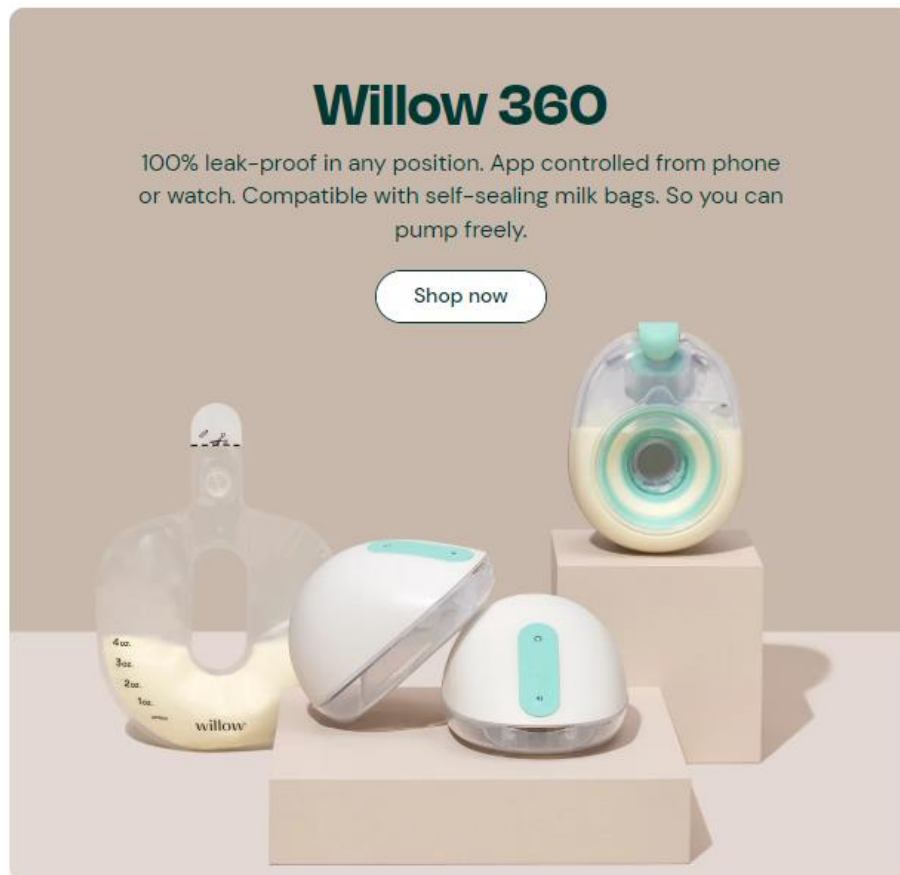
214. None of Elvie's actions, including its defense of this lawsuit, gives rise to or constitutes an exceptional case under 35 U.S.C. § 285 or enhanced damages under 35 U.S.C. § 284.

TENTH DEFENSE
(Plaintiff's False Advertising and Unfair Competition Claims are Barred)

215. One or more of Plaintiff's false advertising and unfair competition claims are barred by the equitable doctrines of acquiescence, waiver, estoppel, and/or laches.

216. One or more of Plaintiff's false advertising and unfair competition claims are barred by the First Amendment of the United States Constitution.

217. One or more of Plaintiff's false advertising and unfair competition claims are barred by the equitable doctrine of unclean hands. For example, Plaintiff's claims are barred because Plaintiff's advertising of the Willow Breast Pump 3.0 (also known as the Willow 360 Wearable Breast Pump) as "100% leak proof" is false and misleading. See <https://onewillow.com/>.



Willow 360 advertisement, <https://onewillow.com/> (last visited July 3, 2024).

ELEVENTH DEFENSE
(Additional Defenses)

218. Plaintiff's claims are barred and/or limited by any additional defenses that discovery may reveal.

RESERVATION OF DEFENSES

Elvie reserves the right to assert additional defenses as may be warranted by discovery or further factual investigation in this action.

RELIEF REQUESTED

Having answered Plaintiff's Complaint, Defendant Elvie prays for judgment as follows:

- A. That Plaintiff takes nothing by its Complaint;
- B. That judgment be entered in Defendant's favor;
- C. That the Court dismiss each and every claim in Plaintiff's Complaint with prejudice, and that all relief requested by the Plaintiff is denied;
- D. That Defendant be awarded Defendant attorneys' fees and costs incurred in this litigation under 35 U.S.C. § 285 and/or 15 U.S.C. § 1117(a); and
- E. Any further relief as the Court may deem just and proper.

THIRD AMENDED COUNTERCLAIMS

Defendant and Counterclaim Plaintiff Chiaro Technology Ltd. ("Elvie" or "Counterclaim Plaintiff") assert the following amended counterclaims against Counterclaim Defendant Willow Innovations, Inc. ("Willow" or "Counterclaim Defendant").

Nature of the Counterclaims

1. This counterclaim is for willful patent infringement of U.S. Patent Nos. 11,260,151 (the "'151 patent"), 11,357,893 (the "'893 patent"), 11,413,380 (the "'380 patent"), and 11,730,867 (the "'867 patent") (collectively, the "Elvie Asserted Patents"). In addition, this

counterclaim is for declaratory judgment that United States Patent Nos. 10,398,816 (the “’816 patent”), 10,434,228 (the “’228 patent”), 10,625,005 (the “’005 patent”), 10,722,624 (the “’624 patent”), 11,185,619 (the “’619 patent”), and U.S. Design Patent Nos. D832,995 (the “’D995 patent”) and D977,625 (the “’D625”) (collectively, the “Willow Asserted Patents”) are invalid and not infringed by any Elvie product, including the Elvie Pump. Finally, this counterclaim is for infringement of Elvie’s trade dress.

2. Elvie alleges that Willow’s Willow Go product (the “Willow Go”) infringes each of the Elvie Asserted Patents and Elvie’s trade dress.

The Parties

3. Elvie is a company incorporated under the laws of England and Wales and located at 63-66 Hatton Garden, Second Floor, London, EC1N 8LE, United Kingdom.

4. On information and belief, Willow is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1975 El Camino Real, Suite 306, Mountain View, CA 94040.

Jurisdiction and Venue

5. This is an action for patent infringement under 35 U.S. § 271.

6. This Court has subject matter jurisdiction pursuant to 35 U.S.C. § 271 for Elvie’s claims of patent infringement arising under federal law. This Court also has jurisdiction over the subject matter of these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, and 35 U.S.C. § 1 *et seq.*

7. This Court has supplemental jurisdiction over the claims that arise under the laws of the state of Texas pursuant to 28 U.S.C. § 1367(a) because the common law claim of trade

dress infringement is so related to the Federal claims that they form part of the same controversy and are derived from a common nucleus of operative facts.

8. Willow has availed itself of this forum in this action and is therefore subject to personal jurisdiction in this district.

9. Willow purposefully availed itself of the benefit of conducting business in Texas by offering for sale and selling its Willow Go product in the State, including this District, through at least the online market places Amazon.com and shop.onewillow.com.

10. Willow, directly and through subsidiaries or intermediaries (including distributors and/or retailers) has purposefully and voluntarily placed its infringing products into the stream of commerce with the intention and expectation that the infringing products will be purchased for use in Texas and this District. Willow has intentionally targeted Texas, and this District, for its business activities and has purposefully availed itself of the benefits of conducting business in Texas such that it should reasonably anticipate being subject to its law and the jurisdiction of its courts. Further, Elvie's infringement allegations arise out of and relate to Willow's commercial activities in Texas.

11. Venue is proper in this judicial district under §§ 1391 and 1400, and as a result of Willow's choice of forum in filing this action.

Background

A. Elvie's Mission

12. Elvie is an award-winning company that was founded in April 2013 by Tania Boler, an internationally recognized women's health expert, with the mission to revolutionize women's healthcare by developing smarter, "female first" technology that improves the health and lives of women.

13. Since 2013, Elvie has innovated, developed and sold products in women's healthcare categories which have been overlooked for many years, including breast pumps and pelvic floor health. The first product to launch, Elvie Trainer, is an award-winning Kegel trainer and app that helps women strengthen the pelvic floor. Its second product, Elvie Pump, is the world's first silent, wearable breast pump. Elvie Pump launched during the 2018 London Fashion Week when Valeria Garcia walked the runway while wearing the Elvie Pump.

14. By 2017, Elvie was recognized as one of the UK's top 33 startups by TechCityUK and named one of the 15 startups "To Watch" by The Sunday Times. *See* Exhibit 1, Paul Abbott, 33 of the UK's Most Promising Tech Companies Join Upscale 2017, TechNation (Jan. 26, 2017), <https://technation.io/news/upscale-2017/>; Exhibit 2, Research Report 2017, The Sunday Times Tech Track at 23 (accessible at <https://www.m2lasers.com/images/2017-Tech-Track-100-research-report.pdf>). Elvie is committed to continue investing in its innovative products to improve the lives of women around the globe.

B. Elvie's Innovation in the Breast Pump Industry

15. Despite the important function of breast pumps for nursing parents, the breast pump industry remained largely stagnant for decades. *See* Exhibit 3, Sarah Buhr, *Kegel trainer startup Elvie is launching a smaller, smarter, hands-free breast pump*, TechCrunch (Sept. 14, 2018), <https://techcrunch.com/2018/09/14/kegel-trainer-startup-elvie-is-launching-a-smaller-smarter-breast-pump/>.

16. In 2015, Elvie recognized that there was great need for innovation in the breast pump space. At the time, breast pumps were bulky, loud, and often required an electrical outlet. New mothers were in need of a breast pump that could meet the demands of a busy life. Elvie

began investing substantial time and resources to investigate the issues women faced when using existing breast pumps.

17. Elvie determined that women were largely unhappy with the current breast pumps on the market and felt that the available pumps were impractical, difficult to fit into their busy lives, and made them feel like cows. Women wanted a solution that was strong and efficient, while also being quiet and discreet. Women also sought breast pumps that were easy to assemble, use, and clean, while also being portable and comfortable.

18. Elvie sought to give women a better pumping experience than what the current market allowed for and in 2015 began developing a new breast pump that was more suitable to what mothers actually wanted. Elvie's development efforts focused on developing a superior pump that would be discreet and that could be used anywhere, at any time. To achieve these goals, Elvie's design objectives included housing all physical and functional elements of the pump within a single unit that could fit inside a bra. Elvie's numerous other design considerations included a pump that required minimal set-up and that was easy to keep clean.

19. Elvie's development efforts ultimately culminated in the launch of the Elvie Pump in September 2018.

C. Elvie's Launch of the Elvie Pump

20. Taking years of market research and all the above issues into consideration, Elvie developed the Elvie Pump, the world's first silent, wearable breast pump. The Elvie Pump was designed to be "virtually silent," "small enough to fit a standard nursing bra," and "self-contained." *See* Ex. 18, Elvie Pump Introduction.

21. Elvie unveiled the Elvie Pump, on September 15, 2018, which became available for sale in October 2018. An example of the Elvie Pump is shown below.



22. The Elvie Pump was launched on Elvie’s own e-commerce website as well as third party websites, such as amazon.com.

23. Noted as one of “the biggest innovation[s] in pumping technology of the past 100 years,” *see* Elvie, Core77 Design Awards 2019, <https://designawards.core77.com/health-wellness/85273/Elvie> (last accessed May 10, 2023), the Elvie Pump’s trailblazing technology includes a coin-sized pump, sleek design, and the ability to run quietly and discreetly.

24. The Elvie Pump has won over 25 awards for its innovation, including International Design Awards, Mumsnet Awards, Dezeen Awards, Baby Magazine Awards, The Red Dot Awards and Good Design Awards amongst others. *See* Ex. 4.

25. For example, in 2019, TIME named the Elvie Pump as one of the “Best Inventions of 2019” (Exhibit 5); the Core77 Design Awards named the Elvie Pump as a runner up in the category of Health & Wellness (Exhibit 6); and Dezeen named the Elvie Pump the “Wearable Design of the Year.” (Exhibit 7). In 2020, the European Centre awarded the Elvie Pump the ‘Good Design Award.’ (Exhibit 8). Further, in 2022, Forbes named the Elvie Pump the “Best Wearable Breast Pump.” (Exhibit 9).

26. In addition, Elvie Pump allows mothers to control the pump through a phone application. This allows mothers to customize the pump to fit their needs while giving them the freedom to pump whenever and wherever they would like.

27. In order to protect its pioneering technology, Elvie applied for and received numerous patents covering its innovative breast pump, including the Elvie Asserted Patents, which claim priority to a number of Great Britain patent applications filed in June 2017.

The Elvie Asserted Patents

28. On March 1, 2022, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued U.S. Patent No. 11,260,151 (the “’151 patent”), entitled “Breast Pump System.” A true and correct copy of the ’151 patent is attached hereto as Exhibit 10. The ’151 patent was exclusively licensed to Elvie, and Elvie possesses the exclusive right of recovery for any past, present, or future infringement of the ’151 patent, including equitable relief and damages.

29. The ’151 patent claims priority to a number of Great Britain patent applications with priority dates as early as June 15, 2017. The ’151 patent issued from U.S. Patent Application No. 17/203,109 (the “’109 application”) which was filed on March 16, 2021. The ’109 application is a continuation of U.S. Patent Application No. 17/181,057 (the “’057 application”), which was filed on February 22, 2023. The ’057 application is a continuation of U.S. Patent No. 16/009,547 (the “’547 application”), which was filed on June 15, 2018 and later issued as U.S. Patent No. 10,926,011.

30. On June 14, 2022, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued U.S. Patent No. 11,357,893 (the “’893 patent”), entitled, “Breast Pump System.” A true and correct copy of the ’893 patent is attached hereto as Exhibit 11. The ’893

patent was exclusively licensed to Elvie, and Elvie possess the exclusive right of recovery for any past, present, or future infringements of the '893 patent, including equitable relief and damages.

31. The '893 patent claims priority to a number of Great Britain patent applications with priority dates as early as June 15, 2017. The '893 patent issued from U.S. Patent Application No. 17/203,050 (the "'050 application") which was filed on March 16, 2021. The '050 application is a continuation of U.S. Patent Application No. 17/181,057 (the "'057 application"), which was filed on February 22, 2021. The '057 application is a continuation of U.S. Patent Application 16/009,547 (the "'547 application") which was filed on June 15, 2018 and issued as U.S. Patent No. 10,926,011.

32. On August 16, 2022, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued U.S. Patent No. 11,413,380 (the "'380 patent"), entitled, "Breast Pump System." A true and correct copy of the '380 patent is attached hereto as Exhibit 12. The '380 patent was exclusively licensed to Elvie, and Elvie possess the exclusive right of recovery for any past, present, or future infringements of the '380 patent, including equitable relief and damages.

33. The '380 patent claims priority to a number of Great Britain patent applications with priority dates as early as June 15, 2017. The '380 patent issued from U.S. Patent Application No. 17/203,327 (the "'327 application"), which was filed on March 16, 2021. The '327 application is a continuation of U.S. Patent Application No. 17/181,057 (the "'057 application"), which was filed on February 22, 2021. The '057 application is a continuation of U.S. Patent Application No. 16/009,547 (the "'547 application"), which was filed on June 15, 2018 and issued as U.S. Patent No. 10,926,011.

34. On August 22, 2023, the USPTO duly and lawfully issued U.S. Patent No. 11,730,867 (the “’867 patent”), entitled, “Breast Pump System.” A true and correct copy of the ’867 patent is attached hereto as Exhibit 25. The ’867 patent was exclusively licensed to Elvie, and Elvie possesses the exclusive right of recovery for any past, present, or future infringements of the ’867 patent, including equitable relief and damages.

35. The ’867 patent claims priority to U.S. Patent Application No. 17/181,057 (the “’057 application”), which was filed on February 22, 2021. The ’057 application is a continuation of the ’547 application, which was filed on June 15, 2018 and issued as U.S. Patent No. 10,926,011.

Willow’s Wearable Breast Pump Did Not Meet Users’ Needs

36. During the Elvie Pump development process that began in 2015, competitor breast pumps continued to arrive on the market. One example was the Willow Wearable Breast Pump, which was Willow’s first breast pump that launched in January 2017. *See* Exhibit 13. A picture of the Willow Wearable Breast Pump is shown below.



37. On information and belief, Willow obtained a number of patents covering the Willow Wearable Breast Pump, including Willow's Asserted Patents. *See* Exhibit 14, Willow's Patents (<https://onewillow.com/about-willow/patents/#>).

38. However, Willow's Wearable Breast Pump had numerous drawbacks and still lacked critical features that nursing parents wanted. For example, it was loud, heavy, and required single-use plastic bags to collect the milk. *See* Exhibit 15, TechCrunch. (<https://techcrunch.com/2018/09/14/kegel-trainer-startup-elvie-is-launching-a-smaller-smarter-breast-pump/>).

39. Through its research, Elvie had received substantial negative feedback regarding the use of milk bags. A pump design that required the use of milk collection bags would mean that women would need to continue to purchase milk bags for use with the breast pump. The use of milk bags was also inconvenient because it required the user to stop pumping to change out the milk bag once full. Thus, Elvie sought to design a breast pump that integrated the milk collection vessel within the bra itself and excluded the use of milk bags.

40. Willow's Wearable Breast Pump utilized a pump architecture that generated negative pressure via compressing the milkflow path. Specifically, it used compression elements that cycled between moving away from the milkflow tube to increase vacuum and compressing the milkflow tube to decrease vacuum. But Elvie developed an improved pump architecture where the negative pressure was generated by the diaphragm above the nipple tunnel, and not directly in the milk flow pathway. This improvement allowed the negative pressure-generating elements to be isolated from how the milk is expressed. Moreover, Willow's original pump design required the inefficient upward flow of the milk path, which the Elvie Pump does not require.

41. Therefore, after years of development efforts, Elvie launched its Elvie Pump product, which was unprecedented in its ease of use, portability, and superior pump architecture. In comparison to the Willow Wearable Breast Pump, the Elvie Pump was more discreet and portable; it was quiet, did not require any bags, and was half the weight and size of the Willow breast pump. *See* Exhibit 24. With its in-bra, discreet, silent, and wireless design, the Elvie Pump system has changed the way that mothers are able to breastfeed.

Willow's Infringement of Elvie's Asserted Patents

42. Willow, upon seeing the success of the Elvie Pump, began adopting Elvie technology into Willow products. Notably, Elvie's smaller, more discreet architecture and several other features found in the Elvie Pump (and the Elvie Asserted Patents) are now found in Willow's next generation pump, the Willow Go, which was launched in 2022.

43. Unsatisfied with merely copying Elvie's technology and seeking to capitalize on the Elvie Pump's success, Willow filed the instant suit against Elvie asserting patent infringement. Importantly, however, the Elvie Pump does not infringe any of Willow's Asserted Patents, because Willow's claims are narrowly tailored to cover Willow's original, inferior architecture. In contrast, all of the features Willow has copied from Elvie's products are memorialized and protected in Elvie's intellectual property. Willow's unfounded lawsuit asserting irrelevant patents necessitated these counterclaims asserting Elvie's significant and growing patent portfolio.

44. Willow announced the release of the Willow Go device on March 29, 2022. *See* Ex. 19, Willow Go Press Release (<https://onewillow.com/newsroom/willow-expands-product-suite-and-unveils-willow-go-its-fully-in-bra-wearable-breast-pump-for-only-329/>). In its press

release, the Willow Go noted that it was “ultra-quiet and discreet.” *Id.* A photo of the Willow Go is shown below.



45. On information and belief, the Willow Go device is offered for sale and sold within the United States utilizing Elvie’s patented technology.

46. On information and belief, Willow has sold the Willow Go in the United States, including this District and throughout Texas through online marketplaces. For example, the Willow Go is available online at Willow’s own online store at <https://shop.onewillow.com> and Amazon.com. *See* Exhibit 16.

47. Willow describes the Willow Go as “[t]otally in-bra (even the motor)” and “unique because, unlike traditional breast pumps, everything works inside the pump, inside your bra—no external tubes, cords, wires, or dangling bottles.” *See* Exhibit 17 (<https://shop.onewillow.com/products/willow-go-pump-kit>). But these allegedly “unique” features were disclosed several years prior in the Elvie Pump and Elvie’s Asserted Patents.

48. Notably, in its next-generation pump, Willow discarded its original, inferior method of generating negative pressure via compressing the milkflow path. Indeed, on information and belief, the Willow Go is not covered by any Willow U.S. Patents or Patent Applications. *See* Exhibit 14, Willow Patent Page (noting that only the “Willow Wearable Breast Pump” practices the Asserted Patents). Rather, the Willow Go copies the Elvie Pump’s improved pump architecture where the negative pressure is generated by the diaphragm.

Elvie’s Trade Dress

49. Since as early as 2014, Elvie has used a turquoise color called “celeste” in its color scheme consisting of the colors celeste and white (the “Color Scheme”). An example of the color “celeste” is shown below:



50. This color scheme has remained constant for ten years.

51. The Color Scheme is present in Elvie’s world-famous femtech products, packaging, and mobile application (the “app”).

52. Elvie released its first product, the Elvie Trainer, a pelvic floor trainer, and accompanying app in 2014. The trainer is celeste-colored, and the packaging is white, establishing the Color Scheme. Shown below are a photo of the Elvie Trainer and app from Elvie's website when it first launched in late 2014 (left), and a photo of the Elvie Trainer with its packaging (right):



53. The Elvie Trainer was an immediate hit with consumers, and mothers of newborns in particular. Seeking to identify and address additional issues Elvie's existing customers faced, Elvie recognized a great need for innovation in the breast pump space. Elvie began investing substantial time and resources to investigate the issues women faced when using existing breast pumps. Elvie determined that women wanted a breast pump that was strong and efficient, while also being quiet and discreet. Elvie undertook to apply to the breast pump market Elvie's deep expertise, reputation, and experience in the femtech products space.

54. Elvie released its first breast pump product, the Elvie Pump, in September 2018. The Elvie Pump incorporated the Color Scheme into multiple components. A photo of the components of the Elvie Pump, present on Elvie's website for the Pump since 2018, is shown below:



55. The Elvie Pump was another immediate hit with mothers of newborns. A pivotal part of the Elvie Pump's success was that consumers identified the Elvie Pump with the high quality of the already-successful Elvie Trainer. *See Exhibit 27* (<https://www.forbes.com/sites/tanyaklich/2019/04/02/elvie-a-femtech-startup-that-developed-a-wireless-and-wearable-breast-pump-raises-42-million-in-vc/?sh=5ac575432753>).

56. Since the release of the Elvie Pump, Elvie has released four more breast pump products, including the Elvie Stride, Elvie Stride Plus, Elvie Curve, and Elvie Catch.

57. The Elvie Trainer, Pump, Stride, Stride Plus, Curve, and Catch (collectively, the “Elvie Products”) all incorporate the Color Scheme in either the body of the products, the packaging, or both. A present day photo of the Elvie Stride, Stride Plus, Catch, and Curve products and packaging is shown below:



Elvie Stride



Elvie Stride Plus



Elvie Catch



Elvie Curve

58. The Color Scheme is also used for promotional, marketing, and advertising materials for the Elvie Products, among other uses. Although other colors were used for some Elvie accessories, such as the gray bags included in the Elvie Stride Plus, these other colors only supplement the primary use of the Color Scheme.

59. Through Elvie’s continuous use for nearly a decade, the Color Scheme has inherent distinctiveness as a brand identifier for Elvie and signifies the high-quality, innovative goods and services consumers expect from them.

60. The Color Scheme has no function other than to serve as a brand identifier for Elvie.

61. Elvie has owned common law trade dress rights (the “Trade Dress”) in the Color Scheme by virtue of its continuous use in commerce throughout the United States for the past ten years.

Willow’s Infringement of Elvie’s Trade Dress

62. When Willow released its first two products, the Willow Wearable Breast Pump 1.0 and 2.0, Willow incorporated colors which were distinct from Elvie’s Trade Dress. Shown below are photos of the Willow Wearable Breast Pump 1.0, as displayed on Willow’s website in late 2017 (left), and Willow Breast Pump 2.0, as displayed on Willow’s website in early 2019 (right):



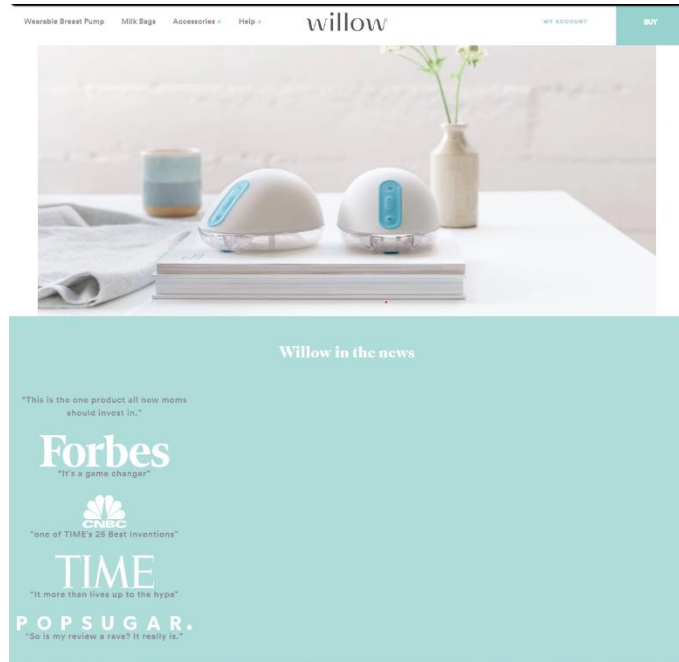
63. The Willow Breast Pump 2.0 was released in February 2019, months after the Elvie Breast Pump launched in September 2018.

64. On information and belief, Willow then sought to leverage the commercial success of the Elvie Breast Pump by copying Elvie’s Trade Dress in order to confuse consumers about the source of Willow’s products and ride the coattails of Elvie’s brand recognition and good will with customers.

65. Willow changed the colors used on its website from the colors used on the Willow Breast Pump 2.0 to those that mimic Elvie's Color Scheme by at least January 2019, before the Willow Breast Pump 2.0 launched. To illustrate, shown below are exemplary photos of Willow's website in October 2018 and January 2019, respectively:¹



Captured Oct. 25, 2018



Captured Jan. 9, 2019

66. Willow completed its transition to Elvie's Color Scheme when it released the Willow Breast Pump 3.0 in April 2020.

67. On information and belief, Willow uses a color scheme for the Willow Breast Pump 3.0 that is confusingly similar to Elvie's Trade Dress.

¹ See Exhibits 28-29 (images of the complete websites).

68. Willow has adopted the colors celeste and white (the “Infringing Trade Dress”) for its website, Willow Breast Pump 3.0, and Willow Go breast pump products. Examples of the Infringing Trade Dress are shown below:



Willow Go

Willow Breast Pump 3.0

69. Willow’s use of the Infringing Trade Dress in connection with its breast pump products is confusingly similar to Elvie’s Trade Dress.

70. Elvie has no agreement of any kind with Willow that would authorize the use of the Trade Dress, nor did Willow ever consult or communicate with Elvie about Willow’s decision to adopt the Infringing Trade Dress.

Willow’s Conduct Is Willful

71. On information and belief, Willow has been knowledgeable about Elvie’s Asserted Patents since their issuance dates.

72. On information and belief, as a competitor in the breast pump market, Willow monitors competitor patent applications, issued patents, and trade dress.

73. On information and belief, Willow monitors the patent applications, issued patents, trade dress, and litigation activity of competitors including at least Elvie.

74. Elvie provides notice of its patents, including the Elvie Asserted Patents, for each of its products through its website in compliance with all statutory requirements, including the requirements of 35 U.S.C. § 287, to pursue and recover for any infringement of the Elvie Asserted Patents. *See* Ex. 20. Elvie's website specifically notes that the Elvie Pump is covered by Elvie's Asserted Patents. *See id.*

75. As a policy, Elvie provides notice of its patents, including the Elvie Asserted Patents, through its website soon after grant. *See, e.g.,* Ex. 20 (Elvie's website specifically noting that, as of August 14, 2023, the Elvie Pump is covered by the '893, '380, and '151 Patents).

76. In the alternative, Willow has had knowledge of Elvie's Asserted Patents and Trade Dress at least as of the filing date of this Counterclaim.

77. Therefore, at least as of the date of this Counterclaim, Willow has had knowledge that its products infringe Elvie's Asserted Patents and Trade Dress.

78. Willow's knowledge of Elvie's Asserted Patents is sufficient to satisfy the knowledge element for induced, contributory, and willful infringement.

COUNT I

Infringement of U.S. Patent No. 11,357,893

79. Elvie realleges and incorporates by reference paragraphs 1-78 of this counterclaim as if fully set forth herein.

80. The '893 patent is directed towards a wearable breast pump system including a housing shaped at least in part to fit inside a bra and an air-pump. Exemplary claim 1 of the '893 patent recites:

A breast pump device that is configured as a self-contained, in-bra wearable device, the breast pump device containing:
a housing that includes:
a battery, and
a pump powered by the battery and generating negative air pressure;

a breast shield made up of a breast flange and a nipple tunnel;
a milk container that is configured to be attached to and removed from the housing; and
a diaphragm configured to be seated against a diaphragm holder that forms a recess or cavity at least in part with an external surface of the housing, the diaphragm deforming in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.

81. Willow has directly infringed and continues to directly infringe one or more claims of the '893 patent in violation of 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing into the United States products that include, but are not limited to, the Willow Go device. For example, the Willow Go includes or performs each and every limitation of at least claim 1 of the '893 patent, either literally or under the doctrine of equivalents.

82. Elvie attaches hereto Exhibit 22 which provide an exemplary claim chart describing how the Willow Go meets the limitations described in claim 1 of the '893 patent.

83. Plaintiff also indirectly infringes one or more claims of the '893 patent in violation of 35 U.S.C. § 271(b) and/or (c) by actively inducing infringement of the Asserted Patent by offering to sell or selling within the United States a device covered by the claims of the Asserted Patent that is not a staple article or commodity of commerce suitable for substantial non-infringing uses.

84. For example, Willow instructs customers of its Willow Go on how to use and operate the Accused Product.

85. Willow's direct and indirect infringement of the '893 patent has been, and continues to be, willful. On information and belief, Plaintiff has been aware of the '893 patent since before the filing of this Complaint and has infringed the '893 patent willfully and deliberately and with knowledge that such conduct violates 35 U.S.C. § 271.

86. Willow's infringement of the '893 patent has damaged, and continues to damage Elvie in an amount yet to be determined, of at least a reasonable royalty and/or lost profits that Elvie would have made but for Willow's infringing acts as provided by 35 U.S.C. § 284.

87. Elvie will suffer irreparable harm unless Willow is enjoined from infringing the '893 patent.

COUNT II

Infringement of U.S. Patent No. 11,413,380

88. Elvie realleges and incorporates by reference paragraphs 1-87 of this counterclaim as if fully set forth herein.

89. The '380 patent is directed towards a wearable breast pump system including a housing shaped at least in part to fit inside a bra and an air-pump. Exemplary claim 29 of the '380 patent recites:

A breast pump device that is configured as a self-contained, in-bra wearable device, the breast pump device comprising:
a self-contained, in-bra wearable device comprising:
a housing that includes:
a rechargeable battery,
a power charging circuit for controlling charging of the rechargeable battery,
control electronics powered by the rechargeable battery,
a pump powered by the rechargeable battery and configured to generate negative air pressure, and
a Universal Serial Bus (USB) charging socket for transferring power to the power charging circuit and the rechargeable battery;
a breast shield made up of a breast flange and a nipple tunnel;
a milk container that is configured to be attached to and removed from the housing; and
a membrane that is configured to define a pumping chamber at least in part with an external surface of the housing, the membrane configured to deform in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.

90. Willow has directly infringed and continues to directly infringe one or more claims of the '380 patent in violation of 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing into the United States products that include, but are not limited to, the

Willow Go device. For example, the Willow Go includes or performs each and every limitation of at least, claim 29 of the '380 patent, either literally or under the doctrine of equivalents.

91. Elvie attaches hereto Exhibit 23 which provides an exemplary claim chart describing how the Willow Go meets the limitations described in claim 29 of the '380 patent.

92. Plaintiff also indirectly infringes one or more claims of the '380 patent in violation of 35 U.S.C. § 271(b) and/or (c) by actively inducing infringement of the Asserted Patent by offering to sell or selling within the United States a device covered by the claims of the Asserted Patent that is not a staple article or commodity of commerce suitable for substantial non-infringing uses.

93. For example, Willow instructs customers of its Willow Go on how to use and operate the Accused Product.

94. Willow's direct and indirect infringement of the '380 patent has been, and continues to be, willful. On information and belief, Plaintiff has been aware of the '380 patent since before the filing of this Complaint and has infringed the '380 patent willfully and deliberately and with knowledge that such conduct violates 35 U.S.C. § 271.

95. Willow's infringement of the '380 patent has damaged, and continues to damage Elvie in an amount yet to be determined, of at least a reasonable royalty and/or lost profits that Elvie would have made but for Willow's infringing acts as provided by 35 U.S.C. § 284.

96. Elvie will suffer irreparable harm unless Willow is enjoined from infringing the '380 patent.

COUNT III

Infringement of U.S. Patent No. 11,260,151

97. Elvie realleges and incorporates by reference paragraphs 1-96 of this counterclaim as if fully set forth herein.

98. The '151 patent is directed towards a wearable breast pump system including a housing shaped at least in part to fit inside a bra and an air-pump. Exemplary claim 1 of the '151 patent recites:

A breast pump device that is configured as a self-contained, in-bra wearable device, the breast pump device comprising:
(i) a housing that includes (a) a battery, and (b) an air pump system powered by the battery and generating negative air pressure;
(ii) a breast shield made up of a breast flange and a nipple tunnel; and
(iii) a milk container that is configured to attach to the housing;
and in which a location of the centre of gravity of the breast pump device is, when in use, below a centre of the nipple tunnel when the milk container is empty.

99. Willow has directly infringed and continues to directly infringe one or more claims of the '151 patent in violation of 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing into the United States products that include, but are not limited to, the Willow Go device. For example, the Willow Go includes or performs each and every limitation of at least, claim 1 of the '151 patent, either literally or under the doctrine of equivalents.

100. Elvie attaches hereto Exhibit 21 which provides an exemplary claim chart describing how the Willow Go meets the limitations described in claim 1 of the '151 patent.

101. Plaintiff also indirectly infringes one or more claims of the '151 patent in violation of 35 U.S.C. § 271(b) and/or (c) by actively inducing infringement of the Asserted Patent by offering to sell or selling within the United States a device covered by the claims of the Asserted Patent that is not a staple article or commodity of commerce suitable for substantial non-infringing uses.

102. For example, Willow instructs customers of its Willow Go on how to use and operate the Accused Product.

103. Willow's direct and indirect infringement of the '151 patent has been, and continues to be, willful. On information and belief, Plaintiff has been aware of the '151 patent

since before the filing of this Complaint and has infringed the '151 patent willfully and deliberately and with knowledge that such conduct violates 35 U.S.C. § 271.

104. Willow's infringement of the '151 patent has damaged, and continues to damage Elvie in an amount yet to be determined, of at least a reasonable royalty and/or lost profits that Elvie would have made but for Willow's infringing acts as provided by 35 U.S.C. § 284.

105. Elvie will suffer irreparable harm unless Willow is enjoined from infringing the '151 patent.

COUNT IV

Infringement of U.S. Patent No. 11,730,867

106. Elvie realleges and incorporates by reference paragraphs 1-105 of this counterclaim as if fully set forth herein.

107. The '867 patent is directed towards a wearable breast pump system including a housing shaped at least in part to fit inside a bra and an air-pump. Exemplary claim 1 of the '867 patent recites:

A breast pump device comprising:

- a self-contained, in-bra wearable device comprising:
 - a housing, the housing comprising
 - a battery, and
 - a pump system configured to be powered by the battery and further configured to generate negative air pressure;
 - a breast shield comprising a breast flange and a nipple tunnel; and
 - a milk container configured to be attached to the housing,
- wherein, in use, the breast shield is configured to contact the milk container and a majority of an inner surface of the housing, the inner surface of the housing configured to face a wearer's breast.

108. Willow has directly infringed and continues to directly infringe one or more claims of the '867 patent in violation of 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing into the United States products that include, but are not limited to, the

Willow Go device. For example, the Willow Go includes or performs each and every limitation of at least, claim 1 of the '867 patent, either literally or under the doctrine of equivalents.

109. Elvie attaches hereto Exhibit 26 which provides an exemplary claim chart describing how the Willow Go meets the limitations described in claim 1 of the '867 patent.

110. Plaintiff also indirectly infringes one or more claims of the '867 patent in violation of 35 U.S.C. § 271(b) and/or (c) by actively inducing infringement of the Asserted Patent by offering to sell or selling within the United States a device covered by the claims of the Asserted Patent that is not a staple article or commodity of commerce suitable for substantial non-infringing uses.

111. For example, Willow instructs customers of its Willow Go on how to use and operate the Accused Product.

112. Willow's direct and indirect infringement of the '867 patent has been, and continues to be, willful. On information and belief, Plaintiff has been aware of the '867 patent since before the filing of this Amended Complaint and has infringed the '867 patent willfully and deliberately and with knowledge that such conduct violates 35 U.S.C. § 271.

113. Willow's infringement of the '867 patent has damaged, and continues to damage Elvie in an amount yet to be determined, of at least a reasonable royalty and/or lost profits that Elvie would have made but for Willow's infringing acts as provided by 35 U.S.C. § 284.

114. Elvie will suffer irreparable harm unless Willow is enjoined from infringing the '867 patent.

COUNT V

Declaratory Judgement of Invalidity of U.S. Patent No. 10,398,816

115. Elvie realleges and incorporates by reference paragraphs 1-114 of this counterclaim as if fully set forth herein.

116. The '816 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or obviousness-type double patenting.

117. This counterclaim arises from an actual and justiciable controversy between Elvie and Willow as to the alleged infringement of the '816 patent. Willow has brought suit against Elvie, alleging that Elvie infringes the '816 patent, as reflected in the Complaint.

118. Elvie is entitled to a declaration by the Court that the '816 patent is invalid.

119. Elvie is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT VI

Declaratory Judgment of Non-infringement of U.S. Patent No. 10,398,816

120. Elvie realleges and incorporates by reference paragraphs 1-119 of this counterclaim as if fully set forth herein.

121. Elvie has not infringed any valid and enforceable claim of the '816 patent, either literally or under the doctrine of equivalents, willfully or otherwise.

122. This counterclaim arises from an actual and justiciable controversy between Elvie and Willow as to the alleged infringement of the '816 patent. Willow has brought suit against Elvie, alleging that Elvie infringes the '816 patent, as reflected in the Complaint.

123. Elvie is entitled to a declaration by the Court that Elvie does not infringe any valid and enforceable claim of the '816 patent.

124. Elvie is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT VII

Declaratory Judgement of Invalidity of U.S. Patent No. 10,434,228

125. Elvie realleges and incorporates by reference paragraphs 1-124 of this counterclaim as if fully set forth herein.

126. The '228 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or obviousness-type double patenting.

127. This counterclaim arises from an actual and justiciable controversy between Elvie and Willow as to the alleged infringement of the '228 patent. Willow has brought suit against Elvie, alleging that Elvie infringes the '228 patent, as reflected in the Complaint.

128. Elvie is entitled to a declaration by the Court that the '228 patent is invalid.

129. Elvie is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT VIII

Declaratory Judgment of Non-infringement of U.S. Patent No. 10,398,228

130. Elvie realleges and incorporates by reference paragraphs 1-129 of this counterclaim as if fully set forth herein.

131. Elvie has not infringed any valid and enforceable claim of the '228 patent, either literally or under the doctrine of equivalents, willfully or otherwise.

132. This counterclaim arises from an actual and justiciable controversy between Elvie and Willow as to the alleged infringement of the '228 patent. Willow has brought suit against Elvie, alleging that Elvie infringes the '228 patent, as reflected in the Complaint.

133. Elvie is entitled to a declaration by the Court that Elvie does not infringe any valid and enforceable claim of the '228 patent.

134. Elvie is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT IX

Declaratory Judgement of Invalidity of U.S. Patent No. 10,625,005

135. Elvie realleges and incorporates by reference paragraphs 1-134 of this counterclaim as if fully set forth herein.

136. The '005 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or obviousness-type double patenting.

137. This counterclaim arises from an actual and justiciable controversy between Elvie and Willow as to the alleged infringement of the '005 patent. Willow has brought suit against Elvie, alleging that Elvie infringes the '005 patent, as reflected in the Complaint.

138. Elvie is entitled to a declaration by the Court that the '005 patent is invalid.

139. Elvie is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT X

Declaratory Judgment of Non-infringement of U.S. Patent No. 10,625,005

140. Elvie realleges and incorporates by reference paragraphs 1-139 of this counterclaim as if fully set forth herein.

141. Elvie has not infringed any valid and enforceable claim of the '005 patent, either literally or under the doctrine of equivalents, willfully or otherwise.

142. This counterclaim arises from an actual and justiciable controversy between Elvie and Willow as to the alleged infringement of the '005 patent. Willow has brought suit against Elvie, alleging that Elvie infringes the '005 patent, as reflected in the Complaint.

143. Elvie is entitled to a declaration by the Court that Elvie does not infringe any valid and enforceable claim of the '005 patent.

144. Elvie is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT XI

Declaratory Judgement of Invalidity of U.S. Patent No. 10,722,624

145. Elvie realleges and incorporates by reference paragraphs 1-144 of this counterclaim as if fully set forth herein.

146. The '624 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or obviousness-type double patenting.

147. This counterclaim arises from an actual and justiciable controversy between Elvie and Willow as to the alleged infringement of the '624 patent. Willow has brought suit against Elvie, alleging that Elvie infringes the '624 patent, as reflected in the Complaint.

148. Elvie is entitled to a declaration by the Court that the '624 patent is invalid.

149. Elvie is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT XII

Declaratory Judgment of Non-infringement of U.S. Patent No. 10,722,624

150. Elvie realleges and incorporates by reference paragraphs 1-149 of this counterclaim as if fully set forth herein.

151. Elvie has not infringed any valid and enforceable claim of the '624 patent, either literally or under the doctrine of equivalents, willfully or otherwise.

152. This counterclaim arises from an actual and justiciable controversy between Elvie and Willow as to the alleged infringement of the '624 patent. Willow has brought suit against Elvie, alleging that Elvie infringes the '624 patent, as reflected in the Complaint.

153. Elvie is entitled to a declaration by the Court that Elvie does not infringe any valid and enforceable claim of the '624 patent.

154. Elvie is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT XIII

Declaratory Judgement of Invalidity of U.S. Patent No. 11,185,619

155. Elvie realleges and incorporates by reference paragraphs 1-154 of this counterclaim as if fully set forth herein.

156. The '619 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or obviousness-type double patenting.

157. This counterclaim arises from an actual and justiciable controversy between Elvie and Willow as to the alleged infringement of the '619 patent. Willow has brought suit against Elvie, alleging that Elvie infringes the '619 patent, as reflected in the Complaint.

158. Elvie is entitled to a declaration by the Court that the '619 patent is invalid.

159. Elvie is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT XIV

Declaratory Judgment of Non-infringement of U.S. Patent No. 11,185,619

160. Elvie realleges and incorporates by reference paragraphs 1-159 of this counterclaim as if fully set forth herein.

161. Elvie has not infringed any valid and enforceable claim of the '619 patent, either literally or under the doctrine of equivalents, willfully or otherwise.

162. This counterclaim arises from an actual and justiciable controversy between Elvie and Willow as to the alleged infringement of the '619 patent. Willow has brought suit against Elvie, alleging that Elvie infringes the '619 patent, as reflected in the Complaint.

163. Elvie is entitled to a declaration by the Court that Elvie does not infringe any valid and enforceable claim of the '619 patent.

164. Elvie is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT XV

Declaratory Judgement of Invalidity of U.S. Design Patent No. D832,995

165. Elvie realleges and incorporates by reference paragraphs 1-164 of this counterclaim as if fully set forth herein.

166. The 'D995 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 102, 103, 112 and/or 171.

167. This counterclaim arises from an actual and justiciable controversy between Elvie and Willow as to the alleged infringement of the 'D995 patent. Willow has brought suit against Elvie, alleging that Elvie infringes the 'D995 patent, as reflected in the Complaint.

168. Elvie is entitled to a declaration by the Court that the 'D995 patent is invalid.

169. Elvie is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT XVI

Declaratory Judgment of Non-infringement of U.S. Design Patent No. D832,995

170. Elvie realleges and incorporates by reference paragraphs 1-169 of this counterclaim as if fully set forth herein.

171. Elvie has not infringed any valid and enforceable claim of the 'D995 patent, either literally or under the doctrine of equivalents, willfully or otherwise.

172. This counterclaim arises from an actual and justiciable controversy between Elvie and Willow as to the alleged infringement of the 'D995 patent. Willow has brought suit against Elvie, alleging that Elvie infringes the 'D995 patent, as reflected in the Complaint.

173. Elvie is entitled to a declaration by the Court that Elvie does not infringe any valid and enforceable claim of the 'D995 patent.

174. Elvie is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT XVII

Declaratory Judgement of Invalidity of U.S. Design Patent No. D977,625

175. Elvie realleges and incorporates by reference paragraphs 1-174 of this counterclaim as if fully set forth herein.

176. The 'D625 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 102, 103, 112 and/or 171.

177. This counterclaim arises from an actual and justiciable controversy between Elvie and Willow as to the alleged infringement of the 'D625 patent. Willow has brought suit against Elvie, alleging that Elvie infringes the 'D625 patent, as reflected in the Complaint.

178. Elvie is entitled to a declaration by the Court that the 'D625 patent is invalid.

179. Elvie is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT XVIII

Declaratory Judgment of Non-infringement of U.S. Design Patent No. D977,625

180. Elvie realleges and incorporates by reference paragraphs 1-179 of this counterclaim as if fully set forth herein.

181. Elvie has not infringed any valid and enforceable claim of the 'D625 patent, either literally or under the doctrine of equivalents, willfully or otherwise.

182. This counterclaim arises from an actual and justiciable controversy between Elvie and Willow as to the alleged infringement of the 'D625 patent. Willow has brought suit against Elvie, alleging that Elvie infringes the 'D625 patent, as reflected in the Complaint.

183. Elvie is entitled to a declaration by the Court that Elvie does not infringe any valid and enforceable claim of the 'D625 patent.

184. Elvie is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT XIX

Declaratory Judgement of Invalidity of U.S. Patent No. 10,668,229

185. Elvie realleges and incorporates by reference paragraphs 1-184 of this counterclaim as if fully set forth herein.

186. The '229 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or obviousness-type double patenting.

187. This counterclaim arises from an actual and justiciable controversy between Elvie and Willow as to the alleged infringement of the '229 patent. Willow has brought suit against Elvie, alleging that Elvie infringes the '229 patent, as reflected in the Complaint.

188. Elvie is entitled to a declaration by the Court that the '229 patent is invalid.

189. Elvie is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT XX

Declaratory Judgment of Non-infringement of U.S. Patent No. 10,688,229

190. Elvie realleges and incorporates by reference paragraphs 1-189 of this counterclaim as if fully set forth herein.

191. Elvie has not infringed any valid and enforceable claim of the '229 patent, either literally or under the doctrine of equivalents, willfully or otherwise.

192. This counterclaim arises from an actual and justiciable controversy between Elvie and Willow as to the alleged infringement of the '229 patent. Willow has brought suit against Elvie, alleging that Elvie infringes the '229 patent, as reflected in the Complaint.

193. Elvie is entitled to a declaration by the Court that Elvie does not infringe any valid and enforceable claim of the '229 patent.

194. Elvie is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT XXI

Common Law Trade Dress Infringement

195. Elvie realleges and incorporates by reference paragraphs 1-194 of this counterclaim as if fully set forth herein.

196. Willow's actions described above, including its manufacture, sale, offer for sale, display and distribution of the Infringing Products constitute common law trade dress infringement of Elvie's Trade Dress under the common law of Texas and other states.

197. Willow's infringement of Elvie's trade dress has been, and continues to be, willful. On information and belief, Willow intentionally changed its products and marketing to resemble Elvie's Trade Dress shortly after Elvie launched the Elvie Pump, which directly competed with Willow's products, in order to take advantage of Elvie's brand recognition and customer good will.

198. As a direct and proximate result of the actions of Willow alleged above, Elvie has been damaged and will continue to be damaged in an amount yet to be determined.

199. Elvie will suffer irreparable harm unless Willow is enjoined from infringing Elvie's Trade Dress.

PRAYER FOR RELIEF

WHEREFORE, Defendant and Counterclaim Plaintiff Elvie requests that this Court enter judgment in favor against Plaintiff and Counterclaim Defendant and grant to Elvie the following relief:

- A. Find that the manufacture, use, offer for sale, sale, and/or importation of Elvie's products have not infringed, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the Willow Asserted Patents;
- B. Find that the claims of the Willow Asserted Patents are invalid;
- C. Find that Plaintiff is infringing Elvie's Asserted Patents in violation of 35 U.S.C. § 271 (a), (b), and/or (c);
- D. Find that Plaintiff is infringing Elvie's trade dress in violation of Texas common law;
- E. Enter an order preliminarily and permanently enjoining Plaintiff, its officers, directors, agents, servants, employees, and all other persons in privity or acting in concert with it who receive actual notice of the order by person serve or otherwise, from any further acts of

infringement of the Elvie Asserted Patents and Trade Dress;

F. Award Elvie damages in an amount adequate to compensate Elvie for Plaintiff's infringement of Elvie's Asserted Patents and Trade Dress, including pre-judgment and post-judgment interest;

G. Treble any and all damages award to Elvie by reason of Plaintiff's willful infringement of the Elvie Asserted Patents pursuant to 35 U.S.C. § 284;

H. Award Elvie interest on damages award and its costs pursuant to 35 U.S.C. § 284;

I. Find that this is an exceptional case and awarding Elvie its reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

J. Award such other and further relief as this Court deems proper.

Execute this 8th day of July 2024.

Respectfully submitted,

/s/ Melissa R. Smith

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that counsel of record who are deemed to have consented to electronic services are being served with a copy of this document via the Court's CM/ECF system per Local Rule CV-5(a)(3) on July 8, 2024.

/s/ Melissa R. Smith
Melissa R. Smith